

Changes in blood pressure among patients in the Ontario Telehomecare programme: An observational longitudinal cohort study

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Abstract

Background: The objective of this study was to investigate the changes in blood pressure among patients enrolled in the Telehomecare programme in Ontario, Canada.

Methods: This observational study utilised a prospective longitudinal cohort design, including patients with heart failure and chronic obstructive pulmonary disease enrolled in the Ontario Telehomecare programme from July 2012 to July 2015. The outcome of interest was change in mean (biweekly) systolic and diastolic blood pressure levels over a six-month period. Patient data were extracted from the Ontario Telemedicine Network database, and analysed using generalised linear mixed model procedures.

Results: Overall, we analysed data for 3513 patients. Patients were on average 74.1 ± 11.4 years of age; almost half were men, 62% had heart failure, 55% chronic obstructive pulmonary disease and 29% diabetes. At baseline, the mean systolic and diastolic blood pressure levels were 130.4 ± 19.1 mmHg and 72.2 ± 12.5 mmHg for the total sample. At six months, the adjusted reduction in systolic and diastolic blood pressure values were 4.0 mmHg (95% confidence interval: -4.5 to -3.5) and 2.7 mmHg (95% confidence interval: -3.1 to -2.4), respectively. In a subgroup of 1220 patients with uncontrolled blood pressure at baseline (systolic/diastolic blood pressure of 150.7 ± 10.2 mmHg/ 80.2 ± 13.5 mmHg) the adjusted reduction in systolic blood pressure was 12.5 mmHg (95% confidence interval: -13.4 to -11.6) and in diastolic blood pressure was 7.1 mmHg (95% confidence interval: -7.8 to -6.5) over the six-month period.

Conclusions: Blood pressure levels were significantly reduced in patients enrolled in the Telehomecare programme, with changes being more pronounced in patients with uncontrolled blood pressure. The sustainability of decreased blood pressure on other clinical outcomes needs further evaluation.

Keywords

Telehomecare, blood pressure, heart failure, chronic obstructive pulmonary disease, longitudinal data analysis

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Introduction

With our aging population, chronic conditions will continue to pose a significant burden on society and the healthcare system.¹ Telemonitoring has been advocated as a useful adjunct to traditional healthcare delivery models for patients with chronic conditions, including uncontrolled blood pressure (BP).^{2,3} Remote collection of real-time health information allows health professionals to continuously monitor patients and adjust treatments, facilitate the early detection of worsening symptoms, and prevent exacerbations.

The Ontario Telehomecare programme was launched in 2007 by the Ontario Telemedicine Network (OTN),⁴

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jointly funded by the Ontario Ministry of Health and Long Term Care (MOHLTC) and Canada Health Infoway. The Ontario Telehomecare programme is a six-month self-management programme designed to remotely support patients with the management of their chronic conditions, with the ultimate goal of reducing health services utilisation. The programme primarily targets patients with heart failure (HF) and chronic obstructive pulmonary disease (COPD), since these two conditions account for the highest volume of hospital readmissions in Canada.⁵ Before the large-scale adoption of the Telehomecare programme in Ontario, the MOHLTC has funded independent comprehensive evaluation of the programme to assess its implementation, adoption and impact on clinical and economic outcomes.

The results of the programme implementation and adoption have been reported elsewhere.⁶ The current study focuses on one of the clinical outcomes.

BP was one of the parameters that was consistently measured and collected in all patients enrolled in the Telehomecare programme. In fact, studies have shown that high BP is prevalent in 70% of HF patients,⁷ and in 42–53% of COPD patients,^{8,9} and continues to be a major modifiable risk factor for cardiovascular mortality and morbidity.¹⁰ A recent meta-analysis of 12 randomised controlled trials (RCTs) of home telemonitoring showed that it may reduce systolic BP by 5.7 mmHg (95% confidence interval (CI): 3.4–7.9) and diastolic BP by 2.8 mmHg (95% CI: 0.2–4.3).³ However, that study and another similar systematic review identified significant heterogeneity across the trials in terms of the study populations and programmes, and highlighted the need for further research.^{2,3} The aim of this study was to investigate the changes in BP among patients with HF and COPD enrolled in the Telehomecare programme in Ontario.

Methods

Study design and population

This observational study utilised a prospective longitudinal cohort design. The study population included community patients with HF and/or COPD enrolled in the Telehomecare programme from July 2012 to July 2015 in three Local Health Integration Networks (LHINs) in Ontario. A LHIN is a geographic catchment area for the centralised administration of healthcare services in Ontario. Patients most frequently were referred to the programme by community care access centres, followed by referrals from the hospitals, healthcare providers or self-referrals. Upon referral, patients were screened for programme eligibility criteria (Supplementary Material, Table S1) by Telehomecare programme staff. For the current study, we excluded patients who did not consent to share their health information for research purposes, and those who stayed in the programme less than two weeks (since the patient data collected within the first two weeks were used as a baseline). If the patient was ‘re-enrolled’

into the programme (defined as a subsequent enrolment after a break >21 days), we only included data from the initial enrolment period.

Telehomecare programme (intervention)

As part of the Telehomecare programme, patients were provided with digital touch-screen tablets connected to a weight scale, pulse oximeter and digital BP monitor (model UA-767PC). On a daily basis, from Monday to Friday, patients took self-measurements of vital signs (i.e. weight, oxygen and BP). All data were automatically transmitted to the central Web platform, where telehomecare nurses could remotely monitor patients.¹¹ An alert was triggered when one of the parameters fell outside the pre-specified threshold; in which case the telehomecare nurse would conduct a phone follow-up with the patient, and communicate with the primary care physician to adjust the care plan, if needed. If no data were transferred, the nurse would contact the patient to clarify the reason for the missing data upload. In addition, nurses conducted health coaching sessions over the phone, focusing on lifestyle modifications (e.g. physical activity level, diet), as well as symptom and medication management. Prior to programme enrolment, patients received training on equipment usage, measurement taking and data transmission. Patients were advised to take their measurements at the same time of the day using the same arm. Educational materials and written instructions were also provided.

Outcome measures and data collection

The primary end-point of our analysis was the change in biweekly mean systolic and diastolic BP levels over the six-month programme duration. The baseline BP levels were defined as the mean of daily measurements for the first two weeks after enrolment.¹² Subsequently, biweekly means were calculated for the remaining six months (25th–26th week measurement being the final). Information regarding patient demographics, clinical characteristics and data on self-measured vital signs were extracted from the database hosted by the OTN. The study protocol was approved by the Ethics Review Board of the University of Toronto (Ref: #30158, 4 June 2014), as well as 19 research sites across the three LHINs.

Statistical analysis

Data were analysed using SAS statistical software (version 9.4, SAS Institute Inc., Cary, North Carolina, USA). Continuous variables were described as means and standard deviations, and compared using Student’s *t*-tests. Categorical variables were described using counts and percentages and compared using the Chi-square test. The change in systolic and diastolic BP levels over the six-month programme period was assessed using generalised linear mixed models (GLMMs). These models can account for within subject correlation typically observed

in longitudinal data, deal with different numbers of observations per patient, handle intermittent missing values, and estimate model parameters using all available information. The estimation for the mixed effects model relies on likelihood methods and as such it works for unbalanced designs, allowing missing data (assuming that data were missing at random).¹³ Therefore, all available data (biweekly average of BP for each patient), including data from participants who subsequently discontinued the study, were used in analyses (hereafter described as ‘intention-to-treat’ cohort).

As a sensitivity analysis, we measured the outcomes for the subset of patients who completed the full six-month programme period (hereafter described as ‘per-protocol’ cohort).

Based on patient baseline systolic and diastolic BP (average of daily measurements for the first two-week period), two subgroup analyses were conducted to evaluate changes in BP over time: (a) for patients with controlled BP, defined as systolic BP < 140 mmHg and/or diastolic BP < 90 mmHg (hereafter abbreviated as <140/90 mmHg); and (b) uncontrolled BP levels ($\geq 140/90$ mmHg).¹⁴

The outcome variables in the models were systolic and diastolic BP levels over a six-month period, including the baseline measurement. Since our exploratory analyses indicated greater improvements in both systolic and diastolic BP levels in earlier weeks of the programme, the time variable (treated as a continuous variable in the model) was logarithmically transformed to fit the data. The models were adjusted for comorbidities (HF, COPD and DM), age and gender. The interactions between these covariates and time were also tested to assess for potential differential effects on blood pressure depending on time. The correlation of patient repeated measurements over time was specified with a spatial exponential variance-covariance matrix.¹⁵ The variance-covariance structure for the models were selected based on the Akaike and Bayesian information criteria.¹⁵ All *p*-values < 0.05 were considered statistically significant.

Results

Between July 2012 and July 2015 there were 4036 patients enrolled in the Telehomecare programme. Of those, we excluded 55 patients who did not consent, and another 468 that only remained in the programme for less than two weeks. In total, data for 3513 patients were analysed. Out of these 3513 patients, 561 were still active in the programme at the time of cohort extraction. Of the remaining 2952 patients, 42% (*n* = 1226) completed the full six-month study period, 6% (*n* = 182) died, and 50% (*n* = 1544) discontinued at earlier stages for different reasons (see Figure 1 and Supplementary Material, Table S2). The comparison of characteristics of patients who completed the full six-month programme versus the remaining cohort (Supplementary Material, Table S3) found no significant differences in age, gender and baseline BP levels. However, there were slightly more COPD

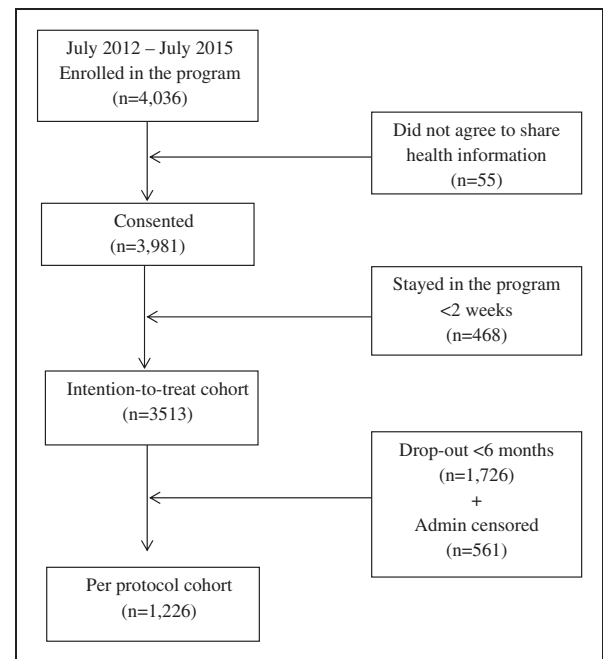


Figure 1. Patient flow chart.

patients among those who did not complete the full duration than among those who completed. The median programme duration of these 3513 patients was 154 days (interquartile range (IQR) = 75–182). The adherence to BP measurements was calculated as a proportion of biweekly submitted self-measurements from the expected number of readings. Adherence was higher among the patients who completed the programme ($86 \pm 22\%$) compared with those who withdrew ($81 \pm 27\%$).

Patient characteristics

Patients were 74.1 ± 11.4 years of age, nearly half were men, 62% had HF, 55% had COPD, and 29% had diabetes. About 17% of patients had a combination of COPD and HF and the other 8% had a combination of COPD, HF and DM. At baseline, the systolic and diastolic BP levels were 130.4 ± 19.1 mmHg and 72.2 ± 12.5 mmHg for the total sample (Table 1). Approximately 35% (*n* = 1220) of the study population had uncontrolled BP levels at baseline: 7% (*n* = 246) had elevated systolic and diastolic BP, 27% (*n* = 900) had elevated systolic BP only; and 2% (*n* = 74) had elevated diastolic BP only. For patients with uncontrolled BP, levels of the mean systolic and diastolic BP were 150.7 ± 10.2 mmHg/ 80.2 ± 13.5 mmHg.

Outcomes

During the programme, the mean systolic/diastolic BP decreased to $126.5 \pm 16.4/69.5 \pm 10.9$ mmHg by the end of 25th–26th week in the ‘intention-to-treat’ cohort. The reduction was attributable to the BP decrease among patients with uncontrolled BP at baseline where mean

Table 1. Patient baseline characteristics.

Characteristics	Total <i>n</i> = 3513	Controlled BP <i>n</i> = 2293	Uncontrolled BP <i>n</i> = 1220	<i>p</i> -value
Age (years), mean (sd)	74.1 (11.4)	74.0 (11.8)	74.2 (10.7)	0.665
Age categories (years), <i>n</i> (%)				
<65	700 (19.9)	475 (20.7)	225 (18.5)	
65–80	1697 (48.4)	1,068 (46.6)	629 (51.6)	0.017
>80	1113 (31.7)	749 (32.7)	364 (29.9)	
Men, <i>n</i> (%)	1739 (49.5)	1198 (52.3)	541 (44.3)	<0.001
Systolic BP, mean (sd)	130.4 (19.1)	119.7 (13.2)	150.7(10.2)	0.001
Diastolic BP, mean (sd)	72.2 (12.5)	68.0 (9.7)	80.2 (13.5)	0.001
Current smoker, <i>n</i> (%) ^a	377 (12.1)	235 (11.7)	142 (12.9)	0.295
HF, <i>n</i> (%)	2186 (62.2)	1465 (63.9)	721 (59.1)	0.005
COPD, <i>n</i> (%)	1923 (54.7)	1200 (52.3)	723 (59.3)	<0.001
Diabetes, <i>n</i> (%)	1012 (28.8)	598 (26.1)	414 (33.9)	<0.001
Other, <i>n</i> (%)	1320 (37.6)	821 (35.7)	499 (41.0)	0.003

BP: blood pressure; COPD: chronic obstructive pulmonary disease; HF: heart failure; sd: standard deviation.

^aMissing data in 11% (*n* = 398) of subjects.

BP values fell to $137.7 \pm 13.3/72.5 \pm 11.1$ mmHg at 25th–26th weeks. Patients with controlled BP levels at baseline remained on average under control over the study course (Table 2, Figure 2). Similar patterns were observed among the ‘per protocol’ cohort (Table 2, Figure 3). More than a half of the patients from the ‘per protocol’ cohort with elevated BP levels at baseline reached controlled BP levels (*n* = 221/420) by the end of six-month programme period. Meanwhile, the vast majority of patients with controlled BP level at baseline remained under the control (*n* = 722/806) over the programme period.

Based on the adjusted GLMM, over the six-month programme, patients experienced a decreasing rate of 1.56 mmHg in systolic BP and 1.05 mm in diastolic BP per log(time) unit (Supplementary Material, Table S4). Over the six-month programme this translates into an estimated 3.99 mmHg (95% CI: –4.52 to –3.47) overall reduction in systolic BP and 2.70 mmHg (95% CI: –3.06 to –2.35) overall reduction in diastolic BP, when adjusted for gender, age, COPD, HF and diabetes (Table 2). The interactions between these covariates and time were non-significant and were removed from the model.

For the ‘intention-to-treat’ cohort with uncontrolled BP levels at baseline, the adjusted reduction was 12.51 mmHg (95% CI: –13.38 to –11.64) in systolic BP and 7.13 mmHg (95% CI: –7.79 to –6.48) in diastolic BP (Table 2 and Supplementary Material, Table S5). Patients with controlled levels of BP at baseline remained under control during the entire study period (Supplementary Material, Table S6). Similar results were observed in sensitivity analyses that included only the patients who completed the full six-month study period (Supplementary Material, Tables S7–S9). Figures 2 and 3 display changes in systolic/diastolic BP levels from baseline to month six months for the ‘intention-to-treat’ and ‘per protocol’ cohorts, respectively.

Discussion

In this observational longitudinal cohort study of telehomecare patients we observed a reduction of approximately 4.0 mmHg (95% CI: –4.5 to –3.5) in systolic BP and 2.7 mmHg (95% CI: –3.1 to –2.4) in diastolic BP over a six-month period. The reduction was attributable to the BP decrease among patients with uncontrolled BP at baseline, who experienced a 12.5 mmHg (95% CI: –13.4 to –11.6) and 7.1 mmHg (95% CI: –7.8 to –6.5) reduction in systolic and diastolic BP levels, respectively. These results might translate into a substantial reduction in cardiovascular risk. A large meta-analysis of 116 trials showed that a 10 mmHg reduction in systolic BP was associated with a 22% reduction in cardiac event risk (Relative Risk [RR] 0.78; 95% CI: 0.73–0.83).¹⁶

Current evidence regarding the effect of telehomecare on BP levels in populations with chronic conditions is diverse. While some RCTs reported substantial reduction in systolic BP levels varying between 11.3 and 14.8 mmHg,^{17–19} others showed a moderate reduction between 4.3 and 6.5 mmHg.^{20–22} Such variations across studies may be due to the differences in study population, multimodalities of telemonitoring interventions, or measurement of outcomes.

Telemonitoring studies reporting larger effects on BP had excluded high-risk patients with severe stages of heart failure New York Heart Association (NYHA III, IV), renal diseases or diabetes.^{17,18} The Ontario Telehomecare programme targeted a high-risk population, as 62% of patients in our sample had HF, 55% had COPD and 30% had diabetes. Furthermore, the programme was not restricted by the baseline BP levels. As a result, about 65% of our study sample had controlled BP levels at programme enrolment. We chose not to exclude these patients from the analysis, since

Table 2. Estimated differences in systolic and diastolic blood pressure (BP) levels.

'Intention-to-treat' cohort			
	Total <i>n</i> = 3513 (95% CI)	Controlled BP <i>n</i> = 2293 (95% CI)	Uncontrolled BP <i>n</i> = 1220 (95% CI)
Systolic BP, baseline	130.44 (129.80–131.07)	119.93 (119.37–120.48)	150.20 (149.61–150.79)
Systolic BP, 25–26th week	126.46 (125.88–127.05)	120.45 (119.80–121.10)	137.71 (136.84–138.58)
Difference from baseline			
Unadjusted	–3.97 (–4.50 to –3.45)	0.52 (–0.06 to 1.11)	–12.49 (–13.36 to –11.62)
Adjusted ^a	–3.99 (–4.52 to –3.47)	0.51 (–0.07 to 1.10)	–12.51 (–13.38 to –11.64)
Diastolic BP, baseline	72.16 (71.75–72.57)	68.17 (67.77–68.58)	79.63 (78.89–80.37)
Diastolic BP, 25–26th week	69.47 (69.08–69.87)	67.86 (67.41–68.32)	72.50 (71.77–73.22)
Difference from baseline			
Unadjusted	–2.69 (–3.05 to –2.33)	–0.31 (–0.70 to 0.08)	–7.08 (–7.75 to –6.44)
Adjusted ^a	–2.70 (–3.06 to –2.35)	–0.32 (–0.71 to 0.07)	–7.13 (–7.79 to –6.48)
'Per protocol' cohort			
	Total <i>n</i> = 1,226 (95% CI)	Controlled BP <i>n</i> = 806 (95% CI)	Uncontrolled BP <i>n</i> = 420 (95% CI)
Systolic BP, baseline	130.69 (129.67–131.71)	120.75 (119.88–121.62)	149.75 (148.76–150.74)
Systolic BP, 25–26th week	126.85 (125.97–127.73)	121.07 (120.13–122.02)	137.93 (136.65–139.20)
Difference from baseline			
Unadjusted	–3.84 (–4.61 to –3.07)	0.32 (–0.52 to 1.17)	–11.82 (–13.05 to –10.59)
Adjusted ^a	–3.84 (–4.61 to –3.07)	0.32 (–0.52 to 1.17)	–11.86 (–13.09 to –10.62)
Diastolic BP, baseline	71.93 (71.28–72.59)	68.36 (67.69–69.04)	78.76 (77.61–79.91)
Diastolic BP, 25–26th week	69.27 (68.69–69.85)	67.79 (67.10–68.48)	72.12 (71.12–73.12)
Difference from baseline			
Unadjusted	–2.66 (–3.15 to –2.17)	–0.57 (–1.11 to –0.03)	–6.64 (–7.51 to –5.76)
Adjusted ^a	–2.66 (–3.16 to –2.17)	–0.57 (–1.11 to –0.03)	–6.66 (–7.53 to –5.80)

CI: confidence interval; COPD: chronic obstructive pulmonary disease; HF: heart failure.

All values are presented as means and 95% CIs in parentheses, and represent BP.

^aAdjusted for age, gender, HF, COPD and diabetes.

the relationship between BP and cardiovascular risk is continuous, and a smaller reduction in BP might translate into a reduction in clinical events, even with relatively low baseline BP values.²³ Instead, we examined the difference of the effect of telehomecare on patients' BP depending on their BP control status at programme entry.

Our results aligned with other telemonitoring studies, as the intervention was shown to be effective among patients with higher baseline BP values. A recent RCT by Green et al. studied the effect of pharmacist-led telemonitoring on BP control over a 12-month period. In a subgroup analysis of patients with systolic BP >160 mmHg, they reported a substantial decrease in systolic (13.2 mmHg, 95% CI: 7.1–19.2) diastolic (4.6 mmHg, 95% CI: 1.2–8.0) BP levels relative to usual care.¹⁷ Similarly, Bosworth et al. studied nurse- and physician-led telemonitoring interventions among US veterans.¹⁹ The largest benefit was observed among patients with poor BP control at baseline, with a 15 mmHg reduction in systolic BP at 12 months.¹⁹

This is the largest longitudinal study that investigated changes in BP among patients enrolled in the Telehomecare programme within Ontario's context. The other large-scale, nurse-led home monitoring programme in Ontario is Heart Institute's Telehome Monitoring Programme run at the University of Ottawa which is targeted for HF patients only.²⁴ The programme manages 300 patients a year and approximately 1700 patients have been enrolled since 2005.²⁵ To the best of the authors' knowledge, to date its impact on BP parameters has not been published.

This is also one of a few telemonitoring studies that has been conducted using home-monitored BP values. Of the 13 telemonitoring studies reviewed by Omboni and Guarda, home monitored BP values were used only in three studies, while others reported office-based measurements.³ According to Powers et al., taking the average of five to six home BP measurements is the most optimal methodology to accurately categorise BP values.²⁶ Evidence also shows that home BP monitoring allows the diagnosis and control of hypertension more accurately than office-based measurements.²⁷

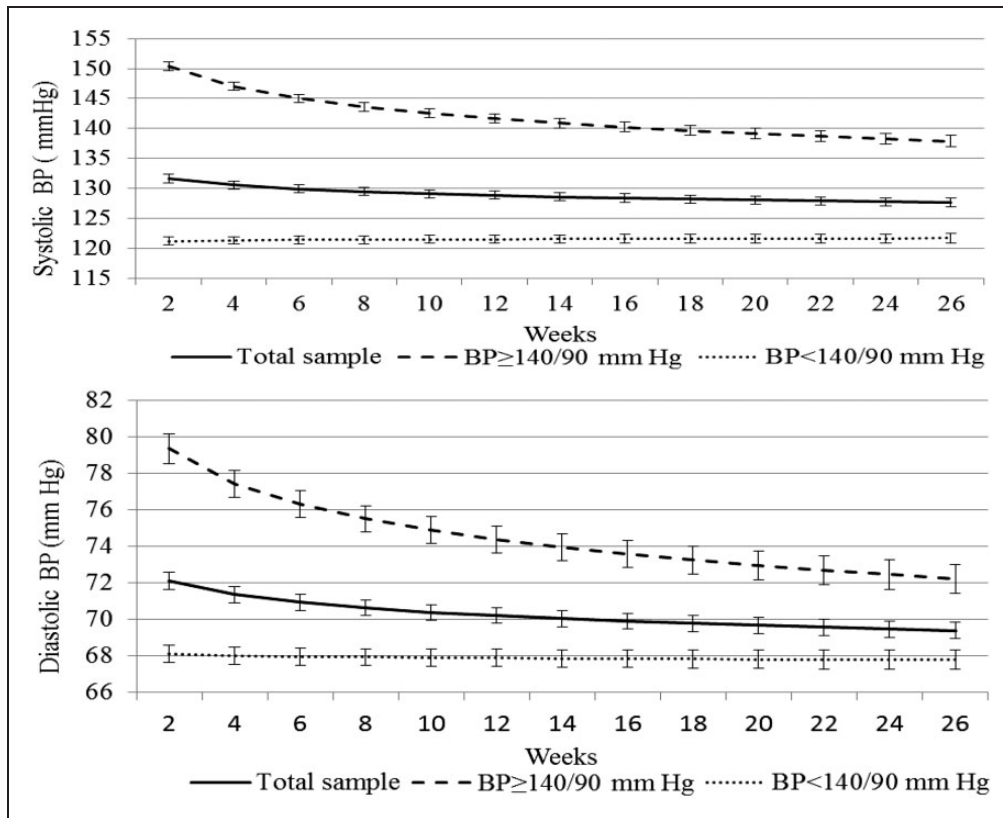


Figure 2. ‘Intention-to-treat’ cohort: biweekly means of systolic and diastolic blood pressure (BP) over programme period, adjusted for age, gender, comorbidities (heart failure, chronic obstructive pulmonary disorder and diabetes). Error bars represent 95% confidence interval.

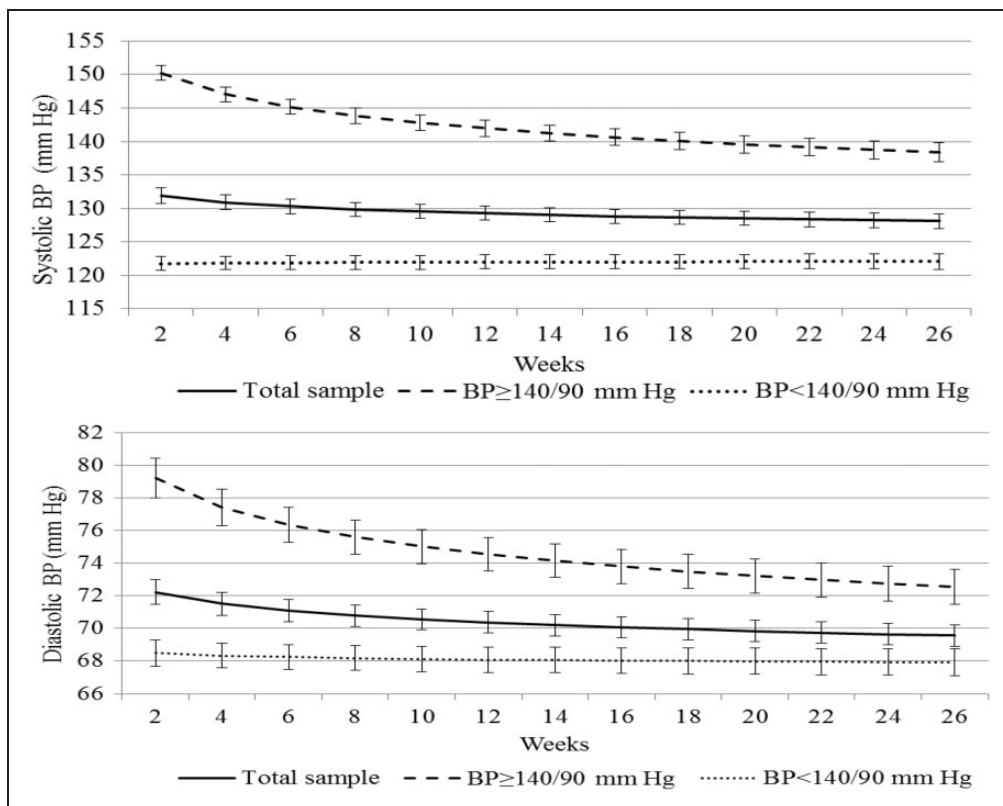


Figure 3. ‘Per protocol’ cohort: biweekly means of systolic and diastolic blood pressure (BP) over programme period, adjusted for age, gender, comorbidities (heart failure, chronic obstructive pulmonary disorder and diabetes). Error bars represent 95% confidence interval.

Our study has limitations that warrant discussion. First, this study was part of a comprehensive programme evaluation, which did not have a control group. That could weaken the study's internal validity; however, we captured BP values consistently over the entire programme period, which enabled us to ensure that changes in BP were not a random variation over time, but rather the effect of the programme itself. Second, the study results might be related to the regression to the mean phenomenon that positively depends on within subject variation.²⁸ However, by using the averages of biweekly measurements, we reduced within subject variation and, therefore, minimised the effect of this bias. Third, the high discontinuation rate of patients might result in overrepresentation of a compliant population in later weeks of the programme, thus introducing the bias. One of the major reasons for programme dropout was that patients requested to leave the programme (Supplementary Material, Table S2). Referring to the personal communication with telehomecare nurses, one of the main reasons was patients' unwillingness or inability to follow the programme requirements. This was further supported by our results, which show that patients who completed the programme showed greater adherence (86%) compared with those who withdrew in earlier period (81%).

A high discontinuation rate might also have biased study results towards better outcomes (i.e. if sick and non-compliant patients dropped out in earlier phases and healthier patients remained in the programme). To address this we compared the baseline characteristics between patients who completed the six-month programme versus those who discontinued prematurely. We found no significant differences in baseline parameters; and observed comparable outcomes in terms of reduction in BP among patients in 'per protocol' and 'intention-to-treat' cohorts. Finally, a limitation was related to inaccuracies in the OTN database, where some variables on patient comorbidities and medication use were not consistently reported and, hence, they were not used in the analysis.

In conclusion, telehomecare is a promising tool to help patients manage their BP. The systolic and diastolic BP significantly decreased among COPD and HF patients with uncontrolled BP at programme entry. That is indicative that patients with elevated BP levels may benefit the most from participating in the Telehomecare programme. The sustainability and effect of decreased BP on other clinical outcomes needs further evaluation.

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