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Efficacy of a Family Nurse-led program on accuracy of blood pressure self-measurement: a randomized controlled trial.

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ABSTRACT

Aims and objectives: this aims to evaluate the efficacy of a Family Nurse-led program on the accuracy of home blood-pressure self-measurement as compared to routine care and management.

Background: home blood-pressure self-measurement are playing an increasingly role for monitoring hypertensive patients, however, previous studies reported poor patients' adherence to current guidelines. A nurse-led training program in the community setting could be an effective strategy to achieve high level of patients' adherence to recommendation.

Design: a multicenter randomized controlled trial performed according to the CONSORT guidelines.

Methods: 170 patients were randomly allocated into the study group (n=83) and into the control group (n=87). All participants received usual care and a guideline-based educational program; subjects in the study group also received 1-hour training session. Clinical trial registration was done (ClinicalTrials.gov.: blinded for Referee).

Results: at baseline (T0), the level of adherence to the recommendation was similar in the two groups. After one month (T1), guideline adherence significantly increased in the intervention group, with respect to blood pressure measurement at the same hour and from the same arm, in a quiet environment, with the back and uncovered arm supported and the legs uncrossed; recording BP more than once in each measurement session; keeping a diary of blood presure measurements; use of the appropriate cuff and proper placement of the cuff; and resting for >5 min before performing the measurement ($p<0.05$).

Conclusions: the Family Nurse-led program is effective in improving patients' adherence to guidelines on the correct technique to self-measure blood pressure at home.

Relevance to clinical practice: This program may be added to the existing interventions in the community setting or considered into specifically nurse-led hypertension management models.

Keywords: Hypertension; nurse-led intervention; home blood pressure measurement; randomized controlled trial.

1. INTRODUCTION

The diagnosis and control of hypertension depend on accurate measurements of blood pressure (BP), which is traditionally done by healthcare workers in different ambulatory care settings, including general practice clinics (Al-Gelban et al., 2011; Baguet, 2012). An important consideration in the diagnosis of hypertension is distinguishing true hypertension from "white coat syndrome," as the latter can lead to over-diagnosis and unnecessary treatment. Accordingly, alternative approaches to measuring BP, such as ambulatory blood pressure monitoring or home blood-pressure self-measurement (HBPM), are gaining increasing acceptance in the diagnosis of hypertension and the monitoring of hypertensive patients (Helvaci & Seyhanli, 2006; Stephan, Gaertner & Cordeanu, 2015; Wagner, 2017). With the new technologies that have recently become widely available, such as automatic and semi-automatic devices, the self-measurement of blood pressure by patients at home has become commonplace (McManus et al., 2014). Furthermore, current guidelines recommend HBPM to improve patient compliance with treatments and care plans (Mancia et al., 2013; Williams et al., 2018) but also to reduce medical costs and the number of visits to ambulatory care centers (Celis, Hond & Staessen, 2005; Staessen, Wang, Bianchi, & Birkenhager, 2003). HBPM has been shown to contribute to hypertension management and control (Manzoli, Pizzi, Flacco & Cicolini, 2013; Obara, Ohkubo, Mano, Kuriyama & Imai, 2013) by avoiding an under- or over-estimations of BP levels and therefore potentially inappropriate drug prescriptions by physicians (Al-Gelban et al., 2011; Manzoli et al. 2012). Moreover, out-of-office HBPM empowers patients to play a pivotal role in managing their own health, in turn increasing patient engagement in BP management (Liyanage-Don, Fung, Phillips & Kronish, 2019).

2. BACKGROUND

To achieve accurate BP measurements at home, measurement guidelines must be closely followed (Mancia et al., 2013; Parati et al., 2008; Wagner, Toftegaard, & Bertelsen, 2012; Williams et al., 2018). However, previous studies have shown that patient compliance is in most cases unsatisfactory (Celis et al., 2005; Flacco et al., 2015; Imai et al., 2003; Jones, Appel, Sheps, Roccella, & Lenfant, 2003; O'Brien et al., 2003; Wagner, Buus, & Jespersen, 2013; Wagner et al., 2014; Wagner et al., 2012), resulting in a higher risk of invalid BP readings and therefore inaccurate diagnosis and management (Liyanage-Don et al., 2019). By contrast, the quality of HBPM was found to be higher in patients who received some form of training in BP measurement from healthcare professionals than in patients who did not receive training (Flacco et al., 2015). Although self-estimation of BP may be prone to error, this risk can be minimized through adequate patient education and training that includes simple but nonetheless important recommendations (Carey, Muntner, Bosworth & Whelton, 2018; Whelton et al., 2018).

A recent study of the efficacy of a nurse-led hypertension management model demonstrated that a nurse-led intervention specifically tailored for implementation in the community healthcare setting is an efficient approach to improve self-care behaviors and reduce BP in hypertensive patients (Zhu, Wong & Wu, 2018). However, there have been few empirical-evidence-based studies on the pivotal role of nurses in improving patient adherence to HBPM recommendations. Also unclear is whether specific training offered by nurses, especially family nurses and specialist hypertension nurses, who frequently have a close relationship with their hypertensive patients (Dean, Kerry, Khong, Kerry & Oakeshott, 2014), could result higher patient adherence to HBPM recommendations.

2.1. Aim of the study and hypotheses

The aim of this study was to evaluate the efficacy of a family nurse (FN)-led home blood pressure management (HBPM) training program in improving BP control based on a comparison with routine care and management.

The research hypothesis was that a specifically tailored training program conducted by a FN, when provided in addition to usual care, could improve patient adherence to HBPM recommendations.

3. METHODS

3.1 Study design, participants, recruitment, and randomization

A single-blind, multicenter, randomized controlled trial was carried out from September 2016 to September 2017 that included all adult (18–85 years) patients with a medical diagnosis of hypertension who visited one of two family practice offices located in Chieti or Pescara (two major cities of the Abruzzo region). Other inclusion criteria were: patients recommended by their general practitioner (GP) or a specialist for HBPM, able to speak and read Italian, having an active phone number, and able to provide written informed consent. Exclusion criteria were: mental illness, cognitive impairments, pregnancy, or institutionalization (e.g., in a nursing home). After enrollment, the patients were randomized into control and intervention groups using computer-generated random tables (NCSS PASS 11 software). The randomization process was managed by the statistical unit of our hospital and all investigators were blinded to the group assignments.

The randomized trial met the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines (see File S1).

3.2. Usual Care

Participants in both groups were guided by two teams made up of a GP and a FN associated with the respective family practice offices (Chieti and Pescara). Each patient received usual care and was required to attend a routine follow-up visit one month after enrollment (T1). Usual care consisted of verbal and written instructions during which the FN or GP advised the patient to follow the recommendations regarding correct HBPM (Parati et al., 2008): *(a)* to measure BP in a calm environment, without distractions or noise; *(b)* to remain silent during the measurement, (*c*) to site without crossing the legs, with the patient's back supported by a chair or headboard and the patient's arm supported and positioned at the same height as the heart; *(d)* to use a BP cuff chosen

on the basis of the arm circumference; *(e)* to avoid drinking coffee or smoking 1 h before BP measurement (Box 1). A written summary of the recommendations (Parati et al., 2008) was given to all participants by the GP or FN at the end of the training program.

3.3. Intervention

In addition to receiving the usual care, patients in the intervention group participated in a 1-h training program (detailed below) conducted by the FN in a dedicated room of the ambulatory care centers. During the program, the nurse instructed patients on how to self-measure BP using the BP self-measurement device and on the importance of adequate device maintenance. The intervention was carried out by the FN on a daily basis during outpatient visits of the participants to the GP. The FN was responsible for coordinating follow-up visits, carried out the educational and training program, and recorded the baseline (T0) data of the patients. All data were collected through face to face interviews using both a structured form for socio-demographic variables (age, sex, marital status, education, family situation and telephone number for follow-up contact) and a structured questionnaire (Flacco et al., 2015), also administered by the FN, to assess the habits and HBPM compliance of the patients at T0 and T1.

3.4. Training program

The training program was performed in accordance with current guidelines (Parati et al., 2008) and consisted of a 1-h session led by one FN (one for each center) tasked with instruction of the patients as described above. During the training program the FN emphasized that since morning and evening BP values can widely differ, especially in patients taking medications, BP should be measured twice a day, in the morning and at evening, at specific fixed times (between 6:00 am and 9:00 am and between 6:00 pm and 9:00 pm) at least during the first week of monitoring (Powers et al., 2011). Thereafter, measurements can be taken before antihypertensive drugs are taken.

3.5. Outcome assessment

The efficacy of the training program was evaluated at T0 and T1 using a structured questionnaire (Flacco et al., 2015) specifically designed to determine patient adherence to current Italian

guidelines on HBPM (Parati et al., 2008). The accuracy of the patient's self-measurement of BP was established both through direct observation of the technique by the FN, and collecting information on adherence to HBPM guidelines as directly reported by patients.

3.6. Sample size estimation

The main outcome was adherence to the recommendations for correct HBPM. Based on Flacco et al. (2015), 52.8% of all participants (undergoing an educational intervention or not) were expected to comply with ≥10 of the HBPM guidelines. Therefore, assuming an alpha error of 0.05, an adherence rate of 52.8% in the control group and a 25% improvement thereof in the intervention group, the inclusion of 54 patients per group was considered adequate to achieve a statistical power of 80%. To account for a 10% dropout rate, the study population was conservatively composed of 60 patients per group, such that 120 patients were enrolled. The appropriate sample size was calculated using NCSS PASS 11 software.

3.7. Statistical analysis

The normal distribution of all continuous variables was assessed using the Shapiro-Wilk test. Differences between groups at baseline and at the 1-month follow-up were analyzed using a chi-squared test for categorical variables, and a t-test and Kruskal-Wallis test for normally and non-normally distributed continuous variables, respectively. Comparisons between the two groups at baseline and at the one-month follow-up were based on the Kruskal-Wallis test, and the statistical significance within each group (pre-post difference) was evaluated using the Wilcoxon matched-pairs signed-ranks test. Statistical significance was set as a two-tailed p-value <0.05 in all analyses. All of the statistical analyses were performed using IBM SPSS statistical software for Windows, version 22.

3.8. Ethical consideration

The study protocol was approved by the local Independent Ethics Committee of (blinded for Referee) in Italy (November 19, 2015) and was registered with ClinicalTrials.gov.: (blinded for Referee).

4. RESULTS

4.1. Characteristics of the sample and procedures at baseline

Of the 215 eligible patients, 170 agreed to participate, with 87 randomly allocated to the usual-care group and 83 to the intervention group (Figure 1). There were no significant differences between the two groups at baseline with respect to mean age, sex, marital status, living status, and educational level (all $p>0.05$; Table 1). Among patients in the usual-care group 57% and among those in the intervention group 44.6% reported having no previous instruction on the correct performance of HBPM ($p>0.05$). For the patients who had received instruction, it most commonly came from a physician or pharmacist ($p>0.05$). Occasional home measurement of BP without following a fixed schedule was reported by 60.5% of the patients in the usual care group and 50.6% of those in the intervention group ($p>0.05$) (Table 2).

4.2. Adherence to HBPM guidelines at baseline

At baseline, the level of adherence to the 15 HBPM practices was similar between the two groups, without significant differences in any of the recommended practices, except for questions number 13 and 14 ($p<0.05$). Seven recommendations were followed by >60% of patients (measurement of BP at different times of day, use of the same arm and same body position to measure BP, use of a cuff chosen on the basis of the patient's arm circumference, correct positioning and support of the arm during BP measurement), but seven were followed by less than 60% of the patients (repeating the measurement after several minutes, keeping a measurement diary, resting for at least 5 min before BP measurement, remaining quiet during the measurement, keeping the legs uncrossed, and sitting supported by a chair or headboard during BP monitoring, with the point where the cuff was located uncovered) (Table 3).

4.3. Efficacy of the family nurse intervention

Compared to baseline, after one month (T1) professional involvement in HBPM instruction differed significantly ($p<0.001$) between the two groups, as instruction was provided to all patients in the intervention group by a FN, in accordance with the study design. After instruction by the FN, the

adherence of patients in the intervention group to the guidelines increased significantly for the following recommendations: BP measurement at the same hour of the day; without talking, with the patient's back supported by a chair or bed saddle; with the patient's legs uncrossed; with the patient's arm positioned at the same height as the heart; more than one BP measurement in each session; keeping a measurement diary; choosing the appropriate cuff and placing it properly on the arm; resting for >5 min before the measurement (all $p<0.001$); with the patient's arm supported ($p<0.01$) and using the same arm ($p<0.05$) with the point where the cuff was located uncovered ($p<0.05$),; There was no improvement in the use of a cuff chosen on the basis of the patient's arm circumference, always measuring BP in the same body position and in a quiet, undisturbed environment. The results are reported in Tables 4 and 5.

5. DISCUSSION

This study evaluated the efficacy of a training program conducted by a FN in improving patient adherence to the current recommendations on HBPM. The results showed a significant improvement of several practices recommended by the HBPM guidelines (Parati et al., 2008). Specifically, in > 70% of the patients in the intervention group, 12 of the 15 procedures were correctly followed one month after FN intervention: use of the same arm, proper choice of cuff, not talking during the measurement, support of the arm and body position, use of a back support, no clothes covering the cuff, BP measurement consistently at the same time of day, measurement repetition after several minutes, and ≥ 5-min rest before the measurement. In general, guideline adherence also improved in the usual care group, but only for one specific item: performing the measurement in a calm environment with no distractions (98.9%) However, only a small percentage of patients (≤30%) in the usual care group complied with the required 5-min rest before the first measurement, repeating the measurement after several minutes, keeping a measurement diary, using a back support. These results are consistent with those of other studies (Flacco et al., 2015; Wagner et al., 2012; Wagner et al., 2013; Wagner et al., 2014) of the appropriateness of HBPM, which

similarly found a low level of adherence with current recommendations. Flacco et al. (2015) suggested patient training in HBPM especially for the less-frequently followed recommendations, such as the importance of performing the measurement more than once. This suggestion is supported by studies showing a difference in systolic BP of ≥10 mmHg between temporally close measurements in 30% of patients (Cicolini et al., 2011) and a 40% probability of misdiagnosis when only single measurements are made (Powers et al., 2011). Other studies have similarly recommended that healthcare workers educate patients regarding the importance of measuring BP after a period of rest (Badeli & Assadi, 2014) and always at the same time of day, in order to avoid the risk of an overestimated BP and a misdiagnosis caused by circadian variations (Verdecchia et al., 1990). Other important instructions are the need for back support and uncrossed legs during BP measurement as both can falsely increase pressure levels (Cushman, Cooper, Horne & Meydrech, 1990; Peters, Binder & Campbell, 1999).

Our finding of a benefit of FN intervention in improving adherence to HBPM guidelines is in line with the conclusions of other studies that evaluated similar strategies to manage hypertension (Hebert et al., 2012; Irewall et al., 2015; Irewall et al., 2019; Sharrief et al., 2019; Zhu, Wong & Wu, 2014; Zhu et al., 2018) or in cardiovascular disease prevention (Cicolini et al., 2013). However, a novel aspect of our study was the use of an educational program as an effective approach to hypertension management. The hypertension training program consisted of a specific curriculum developed for implementation by nurses to expand their role in hypertension management while allowing greater responsibility and a closer interaction with patients (Miao, Wang, & Liu, 2020).

5.1. Limits

This study also had several limitations that should be noted. First, the evaluation period lasted only one month; whether the benefits derived from the educational program persist, decrease, or even disappear over a longer period remains to be determined. Second, the FN-led intervention was tested only in two centres of an Italian community setting, which could limit the generalizability of

our results to a larger population. Third, whether additional training is needed to maintain an adequate level of adherence with HBPM recommendations was not investigated. Fourth, the instrument used for data collection included a section in which patients self-report their habits, such that recall bias or social desirability bias cannot be excluded (Brener, Billy & Grady, 2003). However, a strength of this study was that it employed a procedure conducted by a FN who was able to directly assess the habits and performance of the patients using a measurement instrument to evaluate efficacy.

6. CONCLUSIONS

A FN-led training program for HBPM can yield positive results. In our series of hypertensive patients who participated in a training program, a large and statistically significant improvement in adherence with 12 out of 15 HBPM recommendations was determined, with a significant difference compared to the control group. Our results demonstrate the importance of designing targeted and multidisciplinary educational interventions that include general practitioners and FNs who are able to support hypertensive patients at various stages of treatment, including by helping them to develop skills needed to self-measure BP in order to better manage their disease. This will ultimately translate into an improved quality of life for hypertensive patients, through involvement in their own care pathway.

7. RELEVANCE TO CLINICAL PRACTICE

Through individualized training and re-training interventions for hypertensive patients, the challenges faced by hypertensive patients, including the difficulty in controlling and monitoring BP and reducing the risk of developing diseases such as acute myocardial infarction, stroke, kidney and disease, can be competently addressed, thus leading, on the whole to a better quality of life. By correct self-measurement of BP, patients can reduce their clinic visits, a particular advantage for those with limited access to healthcare facilities. The educational program is relatively simply, does

not involve additional costs and, beyond the usual care, requires only a 1-h training session. Thus, given the program's efficacy in improving patient adherence to HBPM, it should be added to existing interventions aimed at supporting patients with hypertension. Moreover, based on the program's results, nurses should be encouraged to develop new training strategies that increase the technical skills of patients with chronic illnesses to enable greater self-management. Further research should focus on the efficacy of educational and training programs and the results then shared within the clinical community.

IMPACT STATEMENT

What does this paper contribute to the wider global clinical community?

- The targeted Nurse-led training program for home blood pressure self-measurement could be a suitable strategy to develop patient's empowerment and skills
- The results of this randomized controlled trial could serve as feasible nursing practice for the management of hypertensive patients in community settings.
- Our findings highlight that the Nurse-led training program for home blood pressure self-measurement, as an educational intervention, improve patients' adherence to guidelines.

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Table 1. Characteristics of the study population at baseline.

Variables	Usual care (n=87)	Intervention (n=83)	p
Mean age in years (SD)	63.7 (16.1)	65.1 (15.1)	>0.05
Male, %	55.2	49.4	>0.05
Marital status, %			>0.05
- Married	82.8	86.7	
- Not married	17.2	13.2	
Living status, %			>0.05
- Alone	17.2	21.7	
- With family	79.3	77.1	
- With caregiver	3.4	1.2	
Education, %			>0.05
- Elementary	41.4	45.8	
- High school	39.1	34.9	
- Graduate	19.5	19.3	

Table 2. Characteristics of blood pressure self-measurement at baseline.

Blood pressure self-measurement	Usual care Yes % (n)	Intervention Yes % (n)	p
Do you received instructions, written or verbal, on the correct use of BP device and the measurement procedure?	43.0 (37)	55.4 (46)	>0.05
From who?			>0.05
- by myself	32.4 (12)	15.2 (7)	

- from friends	0.0 (0)	4.3 (2)	
- from a pharmacist	24.3 (9)	23.9 (11)	
- from a nurse	8.1 (3)	23.9 (11)	
- from a doctor	35.1 (13)	32.6 (15)	
How many BP measurements do you routinely perform?			
>0.05			
- Occasionally, I do not follow a fixed schedule	60.5 (52)	50.6 (42)	
- About 1 per week	18.6 (16)	30.1 (15)	
- About 2 per week	18.6 (16)	18.1 (25)	
- About 1 per day	1.2 (1)	1.2 (1)	
- About 2 per day or more	1.2 (1)	0.0 (0)	

Table 3. Adherence to HBPM guidelines of the two groups at baseline.

Items	**Usual care**	**Intervention**	
	Yes % (n)	Yes % (n)	**p**
Questions asked to participants by the FN			
1 a. Do you measure BP at different times of day?	68.6 (59)	64.6 (53)	>0.05
1 b. When do you measure your BP most frequently?			>0.05
- Before breakfast	42.4 (25)	34.0 (18)	
- After breakfast	39.0 (23)	49.1 (26)	
- Before lunch	10.2 (6)	13.2 (7)	
- After lunch	5.1 (3)	3.8 (2)	
- Before dinner	3.4 (2)	0.0 (0)	
- After dinner	0.0 (0)	0.0 (0)	
2. Do you always measure BP using the same arm?	74.7 (65)	74.7 (62)	>0.05

3 a. Do you always measure BP in the same body position?	87.4 (76)	90.4 (75)	>0.05
3 b. If so, in which body position do you usually measure BP?			>0.05
- Sitting on a chair	92.1 (70)	89.2 (66)	
- Sitting on the bed	6.6 (5)	2.7 (2)	
- Lying	1.3 (1)	4.1 (3)	
- Standing up	0.0 (0)	4.1 (3)	
(value missing)		*1*	
4. Do you repeat the measurement after few minutes?	16.1 (14)	14.5 (12)	>0.05
5. Do you keep a diary of your BP measurements?	23.0 (20)	19.3 (16)	>0.05
Direct observation of the patient' HBP self-measurement by the FN			
6. Did the patient choose the cuff based on his/her arm circumference?	97.7 (85)	96.4 (80)	>0.05
7. Did the patient put the cuff on properly?	70.1 (61)	84.3 (70)	<0.05
8. Before BP measurement, did the patient rest for at least 5 minutes?	20.7 (18)	15.7 (13)	>0.05
9. During BP measurement, was the room calm, with low noise and no distractions?	57.5 (50)	62.7 (52)	>0.05
10. During BP measurement, was the patient silent?	19.5 (17)	31.3 (26)	>0.05
11. During BP measurement, did the patient keep his/her legs uncrossed?	51.7 (45)	41.0 (34)	>0.05
12. During BP measurement, was the patient's back supported by a chair or headboard?	27.6 (24)	22.9 (19)	>0.05
13. During BP measurement, was the patient's arm supported?	80.0 (68)	92.8 (77)	**<0.05**

14. During BP measurement, was the patient's arm positioned at the same height as the heart?	69.0 (60)	88.0 (73)	**<0.01**
15. During BP measurement, was the point where the cuff was located uncovered?	47.1 (41)	55.4 (46)	>0.05

Table 4. Characteristics of blood pressure self-measurement at the follow-up visit.

Blood pressure self-measurement	**Usual care** Yes % (n)	**Intervention** Yes % (n)	**p**
Do you received instructions, written or verbal, on the correct use of BP device and the measurement procedure?	43.0 (37)	95.2 (79)	<0.001
From who?			<0.001
- by myself	32.4 (12)	1.3 (1)	
- from friends	0.0 (0)	0.0 (0)	
- from a pharmacist	24.3 (9)	5.1 (4)	
- from a nurse	8.1 (3)	89.9 (71)	
- from a doctor	35.1 (13)	3.8 (3)	
How many BP measurements do you routinely perform?			
<0.001			
- Occasionally, I do not follow a fixed schedule	59.8 (52)	16.9 (14)	
- About 1 per week	19.5 (17)	22.9 (19)	
- About 2 per week	18.4 (16)	9.6 (8)	
- About 1 per day	1.1 (1)	38.6 (32)	
- About 2 per day or more	1.1 (1)	12.0 (10)	

Table 5. Adherence to HBPM guidelines by the two groups at the follow-up visit.

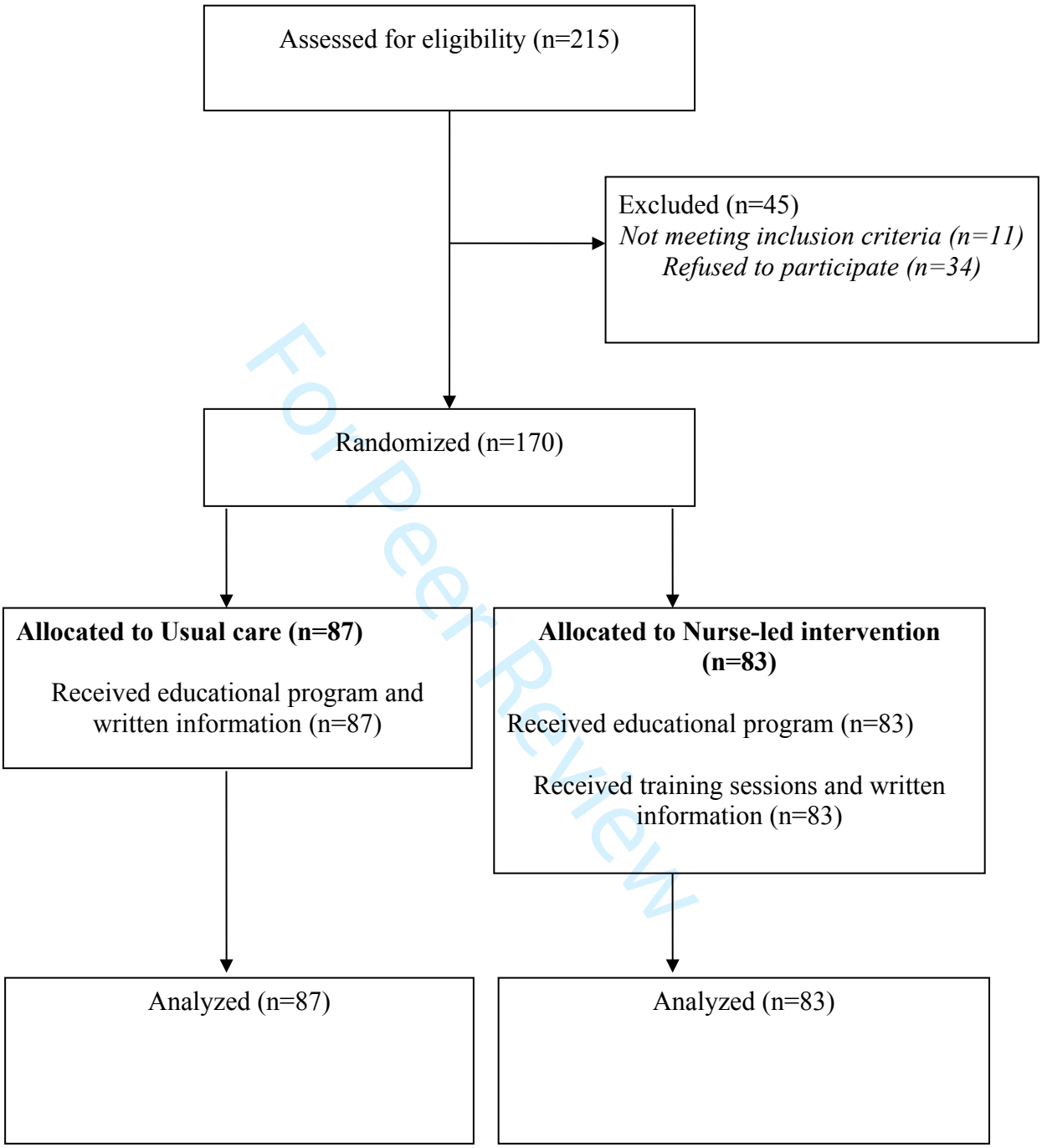
Items	**Usual Care**	**Intervention**	
	Yes % (n)	Yes % (n)	**p**
Questions asked to participants by the FN			
1 a. Do you measure BP at different times of day?	67.4 (58)	24.4 (20)	<0.001
1 b. When do you measure your BP most frequently?			>0.05
- Before breakfast	43.1 (25)	35.0 (7)	
- After breakfast	39.7 (23)	65.0 (13)	
- Before lunch	10.3 (6)	0.0 (0)	
- After lunch	5.2 (3)	0.0 (0)	
- Before dinner	1.7 (1)	0.0 (0)	
- After dinner	0.0 (0)	0.0 (0)	
2. Do you always measure BP using the same arm?	74.7 (65)	86.7 (72)	<0.05
3 a. Do you always measure BP in the same body position?	86.0 (74)	91.5 (75)	>0.05
3 b. If so, in which body position do you usually measure BP?			>0.05
- Sitting on a chair	93.2 (69)	98.7 (74)	
- Sitting on the bed	6.8 (5)	1.3 (1)	
- Lying	0.0 (0)	0.0 (0)	
- Standing up	0.0 (0)	0.0 (0)	
4. Do you repeat the measurement after few minutes?	17.2 (15)	80.7 (67)	<0.001
5. Do you keep a diary of your BP measurements?	21.8 (19)	85.5 (71)	<0.001
Direct observation of the patient' HBP self-measurement by the FN			

6. Did the patient choose the cuff on the basis of his/her arm circumference?	97.7 (85)	97.6 (81)	>0.05
7. Did the patient put the cuff on properly?	70.1 (61)	100.0 (83)	<0.001
8. Before BP measurement, did the patient rest for at least 5 minutes?	21.8 (19)	92.8 (77)	<0.001
9. During BP measurement, was the room calm, with low noise and no distractions?	98.9 (86)	100.0 (83)	>0.05
10. During BP measurement, was the patient silent?	33.3 (29)	86.7 (72)	<0.001
11. During BP measurement, did the patient keep his/her legs uncrossed?	55.2 (48)	91.6 (76)	<0.001
12. During BP measurement, was the patient's back supported by a chair or bed saddle?	23.3 (20)	90.4 (75)	<0.001
13. During BP measurement, was the patient's arm supported?	82.8 (72)	97.6 (81)	<0.01
14. During BP measurement, was the patient's arm positioned at the same height as the heart?	69.0 (60)	97.6 (80)	<0.001
15. During BP measurement, was the point where the cuff was located uncovered?	50.6 (44)	94.0 (78)	<0.001

Box 1. Recommendations provided by the family nurse and general practitioner.

The FN recommends that:
• The BP should be measured in a quiet environment, after a rest period of at least five minutes. • The pressure should be measured on the arm with the highest BP, if the difference in the systolic BP is> 20 mmHg and that of the diastolic > 10 mmHg. • The patient should refrain from drinking coffee or smoking one hour before the measurement and not talk during the measurement. • The legs should not be crossed (Adiyaman et al., 2007); a correct position should be assumed in which the arm rests on a rigid support and is at the same height as the heart. • BP should always be measured in the same body position, as both diastolic and systolic pressure change if the pressure is measured lying down, sitting, or in the Fowler position (Cicolini et al., 2011). • The back should be adequately supported by a chair or headboard; otherwise BP will increase 5–15 mmHg (Cushman et al., 1990). • The cuff and the inner tube should be of adequate dimension and the instrument should be validated. For these reasons, all patients are provided with an updated list of validated home self-measurement tools for BP measurement using the oscillometric method (Dabl®Educational Trust, Blood Pressure Monitors, Validations, Papers and Reviews, 2016). Each patient is given an appropriate size cuff and inner tube.

Figure 1. Flow of participants through each stage of the trial.



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	✓
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	✓
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	✓ p. 3
	2b	Specific objectives or hypotheses	✓ p. 4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	✓ p. 4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	✓ p. 4
	4b	Settings and locations where the data were collected	✓ p. 4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	✓ p. 4,5,6.
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	✓ p. 5,6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	✓ p. 6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	✓ p. 4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	✓
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	✓
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	✓ p. 4,5,6

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	✓ p. 6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	✓ p. 7,8
	13b	For each group, losses and exclusions after randomisation, together with reasons	✓ p. 7,8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	✓ p. 7,8
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	✓
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	✓
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	-
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	✓ p. 7,8, 16-19
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	✓ p. 9
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	✓ p. 8-10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	✓ p. 8-10
Other information			
Registration	23	Registration number and name of trial registry	Blinded for Referee
Protocol	24	Where the full trial protocol can be accessed, if available	ClinicalTrials.gov
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	✓ p. 10

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.