

# Primary care

## Randomised equivalence trial comparing three month and six month follow up of patients with hypertension by family practitioners

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### Abstract

**Objective** To compare blood pressure control, satisfaction, and adherence to drug treatment in patients with treated hypertension followed up by their family physicians either every three months or every six months for three years.

**Design** Randomised equivalence clinical trial.

**Settings** 50 family practices in south eastern Ontario, Canada.

**Participants** 609 patients aged 30-74 years with essential hypertension receiving drug treatment whose hypertension had been controlled for at least three months before entry into the study.

**Results** 302 patients were randomly assigned to follow up every three months and 307 to follow up every six months. Baseline variables in the two groups were similar. As expected, patients in the six month group had significantly fewer visits, but patients in both groups visited their doctor more frequently than their assigned interval. Mean blood pressure was similar in the groups, as was control of hypertension. Patient satisfaction and adherence to treatment were similar in the groups. About 20% of patients in each group had blood pressures that were out of control during the study.

**Conclusions** Follow up of patients with treated essential hypertension every six months is equivalent to follow up every three months. Patient satisfaction and adherence to treatment are the same for these follow up intervals. As about 20% of patients' hypertension was out of control at any time during the study in both groups, the frequency of follow up may not be the most important factor in the control of patients' hypertension by family practitioners.

### Introduction

One of the achievements of contemporary health care is the decrease in morbidity and mortality through the control of chronic cardiovascular conditions such as hypertension. The mortality from cardiovascular disease has fallen by a third over the past 25 years, and although the reasons for this have not been clearly established, control of hypertension may be a central reason.<sup>1</sup> However, control of blood pressure by patients and their doctors is still far from ideal. The Canada heart health survey found that only about 13% of Canadians with hypertension were adequately controlled.<sup>2</sup> This result was even lower than the 25% found in the US National Health and Nutrition Examination Survey (NHANES III).<sup>3</sup> After initial diagnosis and treatment of chronic diseases such as hypertension, most

people need lifelong medical care and follow up, and their doctors must decide how often to follow up for blood pressure control and monitoring of treatment.

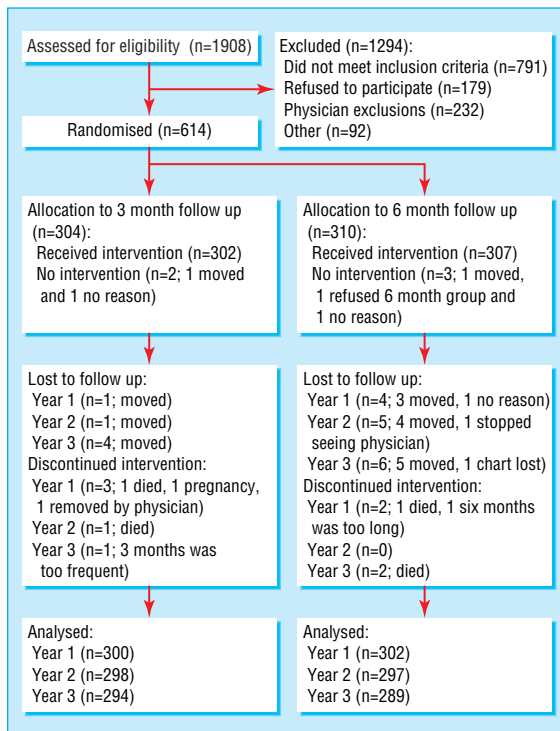
Currently, the suggested intervals for follow up of hypertension come from consensus guidelines. The National Committee on Detection, Evaluation and Treatment of High Blood pressure (JNC7) recommends that once the blood pressure is stabilised, follow up every 3-6 months is appropriate.<sup>4</sup> The British Hypertension Society says that follow up depends on the severity of hypertension, variability of blood pressure, complexity of treatment regimen, patient's compliance with treatment, and the need for non-pharmacological advice. After blood pressure is controlled, follow up every three months should be adequate and the interval should generally not exceed six months.<sup>5</sup> The 1999 Canadian consensus guidelines recommend similar intervals.<sup>6</sup> All of these recommendations are based on level 3 evidence. Several studies have assessed doctors' practices of treating patients with hypertension. Some saw patients every two weeks, some once a year.<sup>7-10</sup> As McDonald has suggested, perhaps the three and six month follow up intervals are based on phases of the moon because nothing better exists.<sup>11</sup>

The hypertension follow up interval study began in November 1997 and ended in July 2002. It is a randomised equivalence trial comparing three month and six month follow up of patients whose essential hypertension had been treated and controlled for at least three months before entry into the study. This was designed as a pragmatic trial of the follow up of people with hypertension. Decisions about treatment after the initial randomisation were left to the family doctor and the patient. The study was designed to determine whether blood pressure control, adherence to treatment, and patient satisfaction were equivalent between the groups after three years of follow up. We also assessed cost of care, which will be addressed elsewhere. The figure shows the flow of patients through the trial.

### Methods

#### Study population

One hundred and thirty family doctors in the region of Kingston, Ontario, were asked to participate in the study; 50 agreed and enrolled their patients. Patients were eligible for the study if they were between the ages of 30 and 74, had a diagnosis of essential hypertension, were taking at least one antihypertensive drug, and had controlled blood pressure for at least three months before entry. Control meant blood pressure was <140/90 mm Hg in patients aged 40 or less, <150/95 in



Flow of patients through the hypertension follow up interval study. Patients were followed by chart review and included in the analysis unless they moved or died

patients aged 41-59, and <160/95 in patients aged 60 or more. Since the study was initiated the targets for blood pressure control have changed, and the analysis is based on the current recommended blood pressure threshold of <140/90 for all ages. The exclusion criteria were pregnancy, inability to give informed consent, hypertension follow up by a specialist, and that in the opinion of the family doctor the patient could not be randomized to the six month group because of other medical problems requiring more frequent follow up.

A research assistant identified all hypertensive patients by chart review for each family doctor. The doctor was then asked to identify the patients who could be approached to participate in the study.

**Randomisation and blinding**

Patients were randomised to three month or six month follow up groups. After the research assistant collected baseline data and obtained consent for an eligible patient, the project coordinator assigned the patient of the particular doctor to three month or six month follow up from a predetermined list generated from a random number table. Each group was stratified by doctor, using blocks of eight to ensure that each doctor had equal numbers of patients in the groups and that each study arm had an equal number. Neither the patient nor the doctor could be blinded to the patient's allocation. Blinding the research assistant collecting the baseline data and the statistician analysing the data to the group allocation reduced potential bias. A study nurse provided an independent, blind measurement of blood pressure, collected the patient satisfaction questionnaire, and did pill counts at 18 and 36 months.

**Follow up groups**

Patients were asked to return to their family doctor for follow up of their blood pressure every three or six months, depending on group assignment. The doctor saw the patient earlier if the blood pressure was out of control, if other medical reasons dictated a more frequent follow up, or if there had been a change of drug.

Once blood pressure was again controlled, the patient returned to the assigned visit frequency. Patients were free to visit the doctor at any time.

To ensure a standardised blood pressure measurement, the method of blood pressure measurement was reviewed with all participating doctors and study research nurses at the beginning of the study and a copy of the recommendations of the Canadian Hypertension Working Group was provided.<sup>12</sup>

**Follow up and outcome assessment**

The main outcomes were blood pressure measurements in the doctor's premises and in patients' homes by the research nurse, patient satisfaction, and adherence to medication.

We assessed systolic and diastolic blood pressure as continuous variables; whether the target of <140/90 had been achieved was assessed as a dichotomous variable. We also asked the doctor whether the patient's blood pressure was in control. Patient satisfaction was assessed with a questionnaire developed and validated by Baker.<sup>13 14</sup> This questionnaire consists of 18 items regarding satisfaction with the consultation and 26 regarding satisfaction with the surgery (clinic). These items are used to describe 10 factors related to patient satisfaction. The questionnaire has been used to assess patients' satisfaction in more than 100 general practices in Britain. We added questions and a visual analogue scale that specifically addressed patients' satisfaction with the care of their hypertension and on self measurement of blood pressure. The questionnaire was pretested with family practice patients in Kingston and found appropriate for the Canadian context. Adherence was assessed by pill count at the nurse's visit at entry and 18 and 36 months. If patients had consumed ≥80% of their pills, we considered them adherent. Adherence to treatment was also assessed by questionnaire.<sup>15</sup>

**Sample size and data analysis**

We based the sample size calculation on significance testing to establish equivalence between the follow up groups with the hypothesis that the true difference in blood pressure control between groups was <10%. Randomisation of patients to the two groups was stratified by doctor, which is considered a random effect. This implies that patients' blood pressure measurements by the same doctor were not independent. An intraclass correlation of 0.1 was used to account for this lack of independence in doctors' blood pressure measurements. An α = 0.05 and β = 0.20 were used. This resulted in a sample size requirement of 296 patients per group.

In our intention to treat analysis we compared blood pressure, patient satisfaction, and adherence to assess equivalence between the two groups.<sup>16</sup> We applied generalised estimating equations (GEE)<sup>17-19</sup> to take into account the dependence of patients' blood pressure measurements obtained from the same doctor's practice. We obtained adjusted mean (SE) blood pressure, mean patient satisfaction scores, proportions for dichotomous outcomes for each group, and their corresponding differences between the two groups from the generalised estimating equations models, constructed 90% confidence intervals for the differences, and inferred equivalence when the confidence interval fell within the equivalence margins. The equivalence margin for both systolic and diastolic blood pressure was ±5 mm, and for patient satisfaction and adherence it was ±10%.

**Table 1** Comparison of baseline variables at entry between groups. Values are numbers (percentages) of patients unless indicated otherwise

Variable	3 month group (n=302)	6 month group (n=307)
Mean (SD) age (years)	55.6 (9.9)	56.1 (9.6)
Sex:		
Female	166 (55)	161 (52)
Male	136 (45)	146 (48)
Mean (SD) blood pressure at entry (mm Hg)		
Systolic	141.6 (16.7)	143.3 (16.9)
Diastolic	84.5 (9.7)	84.3 (8.9)
Duration of hypertension (years):		
<1	26 (8.6)	30 (9.8)
1-5	130 (43)	121 (39.4)
6-10	63 (20.9)	63 (20.5)
>10	83 (27.5)	93 (30.3)
Organ damage	39 (12.9)	42 (13.7)
Retinopathy	7 (2.3)	5 (1.6)
Left ventricular hypertrophy	23 (7.6)	25 (8.1)
Transient ischaemic attacks or stroke	12 (4.0)	9 (2.9)
Comorbidity:		
Heart disease	59 (19.5)	59 (19.2)
Diabetes	26 (8.6)	15 (4.9)
Mean (SD) No of drugs taken for blood pressure	1.4 (0.6)	1.4 (0.6)

## Results

Six hundred and nine patients (302 in the three month group and 307 in the six month group) were enrolled by 50 family doctors and followed over an average of 33.6 months. With the pre-defined equivalence margins and the standard errors of the differences between groups, the power for identifying group equivalence (if the groups are truly identical) was over 89% for all the comparisons of blood pressure. For patient satisfaction, most of the scores had over 70% power, but for two (length of consultation and depth of relationship) the data showed more variation with larger standard error.

Baseline variables were similar in the groups (table 1). However, the three month group contained more patients with diabetes.

Table 2 shows that a total of 10 659 visits were made during the study. The six month group had more unscheduled visits for measuring blood pressure and more visits unrelated to blood pressure, although the difference between groups was not significant (8.68 *v* 7.95, *P*=0.23). The six month group had significantly fewer visits to the doctor over the three years (mean 16.2 (SD 8.5) visits in six month group *v* 18.8 (8.1) in three month group, *P*<0.0001). The mean time between visits was 2.16 (2.25) months for the six month group and 1.89 (1.61) months for the three month group.

### Control of hypertension

At 0, 12, 24, and 36 months mean blood pressure measured by doctors during a consultation were equivalent between groups (table 3). The mean blood pressure measurements taken at patients' homes by nurses were similar to the doctors' measurements but were consistently lower in years 2 and 3 (table 4). There was a trend to lower blood pressure readings in both groups after three years for both the doctors' and nurses' measurements.

Table 5 shows the percentage of patients whose blood pressure was out of control as judged by their doctor over the course of the study. Although we provided doctors with

guidelines for levels of blood pressure that should be considered out of control, we asked them to use their own judgment.

### Satisfaction with medical care

All of the factors measured for patient satisfaction were equivalent in the two groups (table 6), as was patients' satisfaction with the care of their blood pressure by their doctor (table 7). More patients in the six month group thought that the doctor did not take their blood pressure problem seriously enough towards the end of the study.

### Adherence to treatment

Adherence to treatment was equivalent between groups. However, we found that pill counts in this pragmatic trial were unreliable. The research nurse found it difficult to determine exactly how many pills some patients who were taking multiple drugs had taken. Table 8 shows results from the compliance questionnaire.<sup>12</sup> At entry, more patients in the three month group forgot to take their blood pressure drug. Otherwise, the groups were equivalent.

### Self monitoring of blood pressure

Sixty per cent of patients in the three month group and 57% in the six month group measured their blood pressure outside of the office setting (home, work, pharmacy). At entry, 36% of patients in the three month group and 39% of the six month group measured their blood pressure at home. By the end of the study, this increased to 52% (three month group) and 47% (six month group).

## Discussion

The findings of this study suggest that six monthly follow up is sufficient for patients with controlled hypertension. In three years of follow up of patients with hypertension, we found that blood pressure control, patient satisfaction, and adherence to treatment were equivalent in patients assigned to follow up at three month and six month intervals.

Patients in both groups visited their doctor more frequently than their assigned follow up times, but the six month group had fewer visits to the doctor overall. Patients in this group had more visits unrelated to hypertension, which suggests that patients given longer intervals between regular appointments see their doctor between these appointments for other reasons. We do not know if these other issues would have been dealt with at the regular hypertension visit if shorter intervals had been used.

By the end of this study, about half the patients in both groups were measuring their own blood pressure. This suggests that doctors are recommending this practice to their patients as part of monitoring their control. We don't know how this affects treatment or follow up of people with hypertension but it is worth further study.

As the study included patients from 50 family doctors in Canada who practise in a variety of rural and urban settings, its findings can be generalised to most family practice settings in North America and Britain.

We found a high rate of inadequately controlled blood pressure in patients in both groups. The higher mean blood pressure at entry and the level of control may result from the higher acceptable targets for blood pressure in older recommendations for control of blood pressure, which were used initially. It may also explain why blood pressure in both groups fell during the 36 months of follow up. Determining the reasons for this fall was not part of this study, but the results suggest that frequency of follow up is not as important in blood pressure control as has

**Table 2** Number of visits to doctor over three years

Group	No of visits	Visits for blood pressure measurement			Mean (SD) visits per patient
		Scheduled	Unscheduled	Other visits	
3 month	5 682	2575	890	2217	18.8 (8.06)
6 month	4 977	1461	939	2577	16.2 (8.45)
Total	10 659	5865	1829	4794	17.5 (8.25)

**Table 3** Mean (SE) numbers of systolic and diastolic blood pressure measurements (mm Hg) in patients with hypertension by family doctors

Time (months)	No of patients	Blood pressure		Difference	Equivalence 90% CI*
		3 month group	6 month group		
<b>Systolic blood pressure</b>					
0	605	140.62 (1.15)	141.16 (1.10)	-0.53 (1.18)	-2.48 to 1.42
12	503	139.82 (1.16)	139.87 (1.08)	-0.05 (1.21)	-2.04 to 1.94
18	494	138.58 (0.95)	139.32 (1.13)	-0.74 (1.09)	-2.54 to 1.05
24	486	140.34 (1.25)	141.51 (1.06)	-1.17 (1.49)	-3.61 to 1.27
36	386	137.55 (1.36)	138.52 (1.12)	-0.98 (1.54)	-3.50 to 1.55
<b>Diastolic blood pressure</b>					
0	605	84.89 (0.56)	83.69 (0.61)	1.21 (0.55)	0.30 to 2.11
12	503	83.55 (0.74)	83.53 (0.61)	0.01 (0.78)	-1.21 to 1.29
18	494	83.55 (0.60)	82.83 (0.70)	0.71 (0.59)	-0.26 to 1.68
24	486	83.48 (0.74)	83.71 (0.63)	-0.22 (0.83)	-1.59 to 1.14
36	386	82.29 (0.66)	81.18 (0.79)	1.11 (0.81)	-0.21 to 2.44

\*If the 90% CI falls entirely within the equivalence range ( $\pm 5$  mm Hg), the groups are considered equivalent.

**Table 4** Mean (SE) systolic and diastolic blood pressure (mm Hg) measured by nurses

Time (months)	No of patients	3 month group	6 month group	Difference (SE)	90% CI*
<b>Systolic blood pressure</b>					
0	608	141.82 (1.36)	143.26 (1.33)	-1.44 (1.35)	-3.65 to 0.77
18	524	134.45 (0.88)	136.08 (1.09)	-1.64 (1.12)	-3.49 to 0.21
36	515	133.50 (1.35)	135.84 (1.23)	-2.35 (1.52)	-4.84 to 0.15
<b>Diastolic blood pressure</b>					
0	608	84.80 (0.68)	84.52 (0.57)	0.28 (0.68)	-0.84 to 1.40
18	524	79.43 (0.57)	78.83 (0.52)	0.60 (0.74)	-0.61 to 1.82
36	515	81.70 (0.91)	81.45 (0.88)	0.25 (1.12)	-1.61 to 2.11

\*If the 90% CI falls entirely within the equivalence range ( $\pm 5$  mm Hg), the groups are considered equivalent.

**Table 5** Number (percentage) of patients whose blood pressure was out of control as judged by doctor

Time (months)	3 month group	6 month group
12	63/302 (21)	52/300 (17)
24	59/299 (20)	67/291 (23)
36	50/275 (18)	41/260 (16)

been thought. The quality of the doctor-patient encounter, the doctor's awareness of guidelines, clinical inertia<sup>20</sup>, and the view of "treating the patient rather than treating the number" may all contribute to the large numbers of known hypertensive patients whose blood pressure is out of control. Further research should focus on these factors.

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Contributors: RVB, MSG, MDD, RIC, ML, SEM, and RS conceived and designed the study. RVB, MSG, RS, LR, and Jean Powers, Margaret Giles, and Xiaofang Ni collected the data, and all authors analysed and interpreted it. RVB, MSG, and ML drafted the article and all authors took part in the revision. RVB, MSG, MDD, RIC, ML, and SEM approved the version to be published. RVB is guarantor.

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**Table 6** Patients' satisfaction with their care. Values are numbers (percentages) unless otherwise indicated

Factor	Time (months)	3 month group		6 month group		Difference (%)	Equivalence 90% CI*
		No	% (SE)	No	% (SE)		
General satisfaction with clinical care	0	294	77 (0.97)	294	76 (1.18)	0.75	-1.05 to 2.55
	36	260	73 (1.24)	257	75 (1.47)	-2.69	-5.76 to 0.38
Professional care	0	292	81 (0.88)	281	81 (0.86)	0.02	-1.62 to 1.65
	36	250	80 (1.05)	254	80 (1.18)	-0.88	-2.96 to 1.93
Depth of relationship	0	290	65 (0.15)	282	65 (1.00)	0.31	-1.53 to 2.16
	36	253	62 (1.05)	254	66 (1.31)	-4.11	-6.57 to -1.66
Length of consultation	0	292	66 (1.37)	293	66 (1.39)	-0.30	-2.48 to 1.89
	36	258	62 (1.76)	251	65 (1.69)	-3.01	-6.57 to 0.55
General satisfaction with the clinic	0	294	76 (0.85)	291	75 (1.11)	0.67	-1.38 to 2.72
	36	261	75 (1.26)	260	74 (1.25)	0.54	-2.31 to 3.39
Premises	0	291	71 (1.13)	285	70 (1.13)	0.83	-1.39 to 3.05
	36	256	68 (1.31)	256	67 (1.35)	0.18	-2.45 to 2.81
Accessibility	0	289	79 (1.25)	293	78 (0.90)	0.86	-1.47 to 2.19
	36	259	76 (1.21)	255	76 (1.32)	0.87	-1.74 to 3.48
Availability	0	292	72 (1.49)	291	71 (1.62)	0.87	-1.58 to 3.32
	36	258	67 (1.67)	260	68 (1.91)	-0.71	-3.58 to 2.15
Medical care	0	287	74 (0.88)	286	72 (0.96)	1.50	-0.20 to 3.20
	36	259	72 (1.04)	254	72 (1.08)	0.11	-2.22 to 2.44
Continuity of care	0	286	71 (2.33)	287	71 (2.48)	0.69	-1.80 to 3.19
	36	256	71 (2.32)	257	69 (2.50)	1.59	-1.70 to 4.90

Number of responses vary due to missing data on questionnaires. The percentages in the patient satisfaction tables are calculated using a regression which describes each factor. The regression equation uses individual question variables from the questionnaire so we can only provide the N for the number of patients used in the analysis and the % does not correspond directly to number of patients.

\*If the 90% CI falls entirely within the equivalence range ( $\pm 10\%$ ), the groups are considered equivalent.

**Table 7** Patients' satisfaction with their doctor's care of their hypertension. Values are numbers (percentages) unless otherwise indicated

Variable	Time (months)	3 month group	6 month group	Difference (% (SE))	Equivalence 90% CI*
My doctor checks my blood pressure often enough	0	280/298 (94)	270/297 (91)	2.61 (1.95)	-0.60 to 5.82
	36	255/263 (97)	247/263 (94)	3.00 (1.30)	-0.87 to 5.13
My doctor does not take my blood pressure problem seriously	0	17/298 (6)	20/297 (7)	-1.03 (2.05)	-4.4 to 2.34
	36	15/263 (6)	23/263 (9)	-3.35 (1.76)	-6.24 to -0.46
I am satisfied with my doctor's care of my blood pressure	0	28/298 (96)	28/297 (94)	2.05 (1.70)	-0.74 to 4.84
	36	252/263 (96)	247/263 (94)	2.28 (1.65)	-0.44 to 5.0
I understand why I have to take medicine to control my blood pressure	0	283/298 (95)	291/297 (98)	-3.04 (1.62)	-5.71 to -0.37
	36	255/263 (97)	255/263 (97)	-0.03 (1.41)	-2.35 to 2.30
Visiting my doctor for my blood pressure takes too much time	0	20/298 (7)	14/297 (5)	1.97 (1.66)	-0.77 to 4.70
	36	20/263 (8)	17/263 (6)	1.09 (2.05)	-2.27 to 4.46

Number of responses vary due to missing data on questionnaires.

\*If the 90% CI falls entirely within the equivalence range ( $\pm 10\%$ ), the groups are considered equivalent.

**Table 8** Adherence to treatment by hypertensive patients. Values are numbers (percentages) of patients unless specified otherwise

Variable	Time (months)	3 month group	6 month group	Difference (% (SE))	Equivalence 90% CI*
Do you ever forget to take your blood pressure pills?	0	110/298 (37)	83/297 (29)	7.50 (3.91)	1.07 to 13.92
	36	78/263 (30)	71/263 (27)	2.96 (3.92)	-3.48 to 9.41
Are you careless at times about taking your medicine?	0	26/298 (9)	24/297 (8)	0.61 (2.04)	-2.74 to 3.96
	36	19/263 (7)	23/263 (9)	-1.56 (2.24)	-5.25 to 2.13
Do you sometimes stop taking your medicine?	0	7/298 (2)	7/297 (2)	0.01 (1.35)	-2.21 to 2.22
	36	3/263 (1)	5/263 (2)	-0.76 (1.24)	-2.80 to 1.28
If you feel worse when you take the medicine, do you stop taking it?	0	17/298 (6)	11/297 (4)	1.92 (1.74)	-0.95 to 4.78
	36	10/263 (4)	12/260 (4)	-0.81 (1.65)	-3.52 to 1.90

Standard error of the difference is estimated by the delta method.<sup>18</sup>

\*If the 90% CI falls entirely within the equivalence range ( $\pm 10\%$ ), the groups are considered equivalent.

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### What is already known on this topic

Recommendations of current hypertension guidelines from Canada, Britain, and the United States for the follow up of patients with stable hypertension are based on expert opinion or usual practice

The decision about the frequency of follow up of a chronic disease such as hypertension has important implications for hypertension control by family doctors and the cost of care

### What this study adds

Follow up of patients with treated hypertension every six months is equivalent to every three months for mean blood pressure, blood pressure control, patient satisfaction, and adherence to hypertensive drugs

Blood pressure of 20% of patients was out of control when assessed at yearly intervals over three years in both groups

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