Original Article

Effectiveness of Interventions Related to Nutrition and Physical Activity in Women with Impaired Fasting Glucose: A Randomized Controlled Community Trial

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Abstract

Objectives: This study determined whether fasting glucose levels in Turkish women with impaired fasting glucose aged 30-65 years could be improved by regular telephone calls reminding them not to consume food with a high glycemic index and to undertake regular physical activity. **Methods:** All subjects/participants in the intervention (n=117) and control (n=99) groups attented a seminar on healthy eating and physical activity. Women in the intervention group were then called weekly and motivated by using charts that were designed with colors adopted from traffic lights. After 12 weeks of intervention both groups were invited for blood tests. In total, 32 intervention and 17 controls responded to this last visit. **Results:** In the intervention group, the numbers of green colour codes for nutrition decreased (from 16.2±4.1 to 15.1±3.7, p=0.03) but the numbers of green colour codes for activity was not changed significantly (from 0.5±0.7 to 0.4±0.7, p=0.25) in the third month. At the third month the fasting blood glucose was higher in the intervention group (117.0±25.8) than in the control group (109.5±9.2) (p=0.69). **Conclusions:** In our study, simple regular telephone calls were not sufficient to motivate the study participants to stay in the study and to take advice about dietary and physical activity. Further studies should be designed to evaluate different and new lifestyle change interventions for high risk individuals in Turkey.

Key Words: Impaired fasting glucose, intervention, glycemic index, physical activity

Bozulmuş Açlık Glukozu Görülen Kadınlarda Beslenme ve Fiziksel Aktiviteye Yönelik Girişimlerinin Etkinliği: Toplum Tabanlı Girişimsel Çalışma

Özet

Amaç: Bozulmuş açlık glukozu saptanan 30-65 yaş kadınlara uygulanan beslenme ve fiziksel aktivite girişimlerinin kişilere düzenli aralıklarla telefon görüşmeleriyle hatırlatılmasının, bireylerde açlık glukoz düzeyini düzeltmedeki etkinliğini incelemektir. **Yöntem:** Tüm girişim (n=117) ve kontrol (n=99) grubuna sağlıklı beslenme şekli ve fiziksel aktivite önerilerini

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içeren bir seminer sunuldu. Seminer sonunda katılımcılara bu önerileri içeren birer broşür verildi. Girişim grubuna ayrıca diyet ve fiziksel aktivite ile ilgili yaşam tarzı önerilerini hatırlatan trafik ışıklarından uyarlanmış renkli haftalık tablolar verildi. Girişim grubundaki kadınlar 12 hafta boyunca haftada bir telefonla arandı. Açlık kan şekeri sonuç değişkeni ise hem girişim hem de kontrol grupları için bakıldı. On iki haftalık izlem sonunda toplam olarak 32 girişim ve 17 kontrol grubu ile araştırma tamamlandı. **Bulgular:** Girişim grubunda 3 aylık izlem sonunda besinlerdeki yeşil renk sıklığında (16.2±4.1'den 15.1±3.7'ye, p=0.03) başlangıca göre istatistiksel olarak anlamlı bir azalma görüldü. Üç ayın sonunda fiziksel aktivitedeki yeşil renk sıklığında (0.5±0.7'den 0.4±0.7'ye, p=0.25) istatistiksel olarak anlamlı bir değişiklik gözlenmedi. Girişim ve kontrol grupları açlık kan şekeri düzeyi açısından 3 aylık izlemin sonunda karşılaştırıldığında girişim grubunun açlık kan şekeri düzeyinin (117.0±25.8) kontrol grubuna (109.5±9.2) göre arttığı (p=0.69) gözlendi. Bu farkın istatistiksel olarak anlamlı olmadığı görüldü. **Sonuç:** Çalışmamızda, sağlıklı beslenme ve fiziksel aktiviteyi artırmak için yapılan düzenli hatırlatıcı telefon görüşmelerinin açlık kan şekeri düzeyini düşürmede etkin olmadığı görüldü. Toplum düzeyinde yapılan girişimsel çalışmalarda katılımı artıracak yeni yöntemler aranmalıdır.

Anahtar Sözcükler: Bozulmuş açlık glukozu, girişim, glisemik indeks, fiziksel aktivite

Introduction

Diabetes mellitus is characterized by high blood glucose concentrations resulting from defects in insulin secretion and/or action.[1-3] Impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) are precursors of diabetes. IFG refers to a condition in which fasting blood glucose is between 100 and 125 mg/dl but is not high enough to be classified as diabetes mellitus.[4] Patients with IGT have a significant risk of developing diabetes and thus are an important target group for primary prevention.[5]

Nutrition and physical activity are important factors in the etiology and management of IGT, and hence of diabetes mellitus.[2] Numerous studies have shown that type 2 diabetes can be prevented among people with IFG or IGT by changes in dietary behaviors and physical activity.[6-8] However, Most of the evidence on effective interventions to prevent diabetes comes from studies conducted in developed countries. The effectiveness of interventions may vary across populations of different social, cultural, and genetic contexts. Our study aimed to determine whether regular telephone calls reminding people not to consume high glycemic index food and to perform regular physical activity impact positively on fasting blood glucose levels in Turkish women with IFG aged 30-64 years.

Methods

The participants were identified in a cardiovascular risk factor survey in İzmir.[9,10] The Balçova Heart Project (BHP) baseline survey was carried out in 2007. The target population was 44607 people over 30 years of age who lived in Balçova. Each household was visited by a trained interviewer and a questionnaire on socio-demographic information, nutrition, cardiovascular risk factors and disease history was administered. Interviewed persons were then invited to a community centre for anthropometric measurements and blood tests. At the end of May 2009 a total of 15911 people had completed the questionnaire and 13290 people had undergone blood tests for lipids and blood glucose levels. The sample size needed for the current study was 128 people (64 participants in each group) assuming 80% power and an effective size of 0.50 (middle).[11] Considering potential losses during the follow-up, all women aged 35-64 years with baseline fasting blood glucose levels between 100-125 mg/dl and lived in two neighborhoods of the Balçova District

(Eğitim and Çetin Emeç) (n=220) were randomized into two groups for the current study. The streets of the two neighborhoods were used as randomization units and divided into intervention and control groups using the block randomization method. Women randomized into the intervention group (N=119) and the control group (N=101) were invited to the local Community Centers. A seminar on healthy eating and physical activity was presented to all the women in the intervention (n=117) and control (n=99) groups by a dietician (SY). The participants did not know in which group they were allocated during the seminar. Figure 1 presents the study recruitment and participation flow chart.

Interventions

In this study a seminar was given to all women on lifestyle changes, including diet and physical activity. A brochure titled 'Lifestyle Balance For Diabetes Prevention' was prepared by the dietician (SY). The brochure was given to each participant at the end of seminar.

The intervention group was taught how to use the weekly color code charts for diet and for physical activity. Members of the Intervention group were phoned weekly during the following three months by the dietician (SY) to monitor the changes in diet and physical activity. After three months the participants were then invited to the local Community Centers for measurements of fasting blood glucose levels. Blood samples were collected by the nurse working in the BHP. The control group only participated in the seminar at the beginning and provided blood glucose samples at the end of the 3 months.

Color code charts

At the beginning of the study color coded charts on nutrition and physical activity were designed for the intervention group by the dietician (SY) to motivate participants for healthy eating and physical activity (Figure 2). Charts included a list of foods that have a high glycemic index and are not recommended for consumption (high in saturated fat etc.) and were created to avoid the risk of diabetes for participants with impaired fasting glucose. Charts included a list of foods and physical activity categories with colors adapted from traffic lights. As traffic lights, it was considered red color means not recommended, yellow color mean moderately recommended and green means recommended. In charts on foods, red signified daily consumption of high glycemic food, yellow 1-6 times per week, and green signified no consumption of high glycemic food. In charts for physical activity categories, red signified no physical activity, yellow 1-4 times weekly, and green 5 times a week. At the end of charts the totals for all colors were presented. Each participant in the intervention group was given two charts each week. The participants filled the total line for food consumption and activity at the end of each week. Women in the intervention group were phoned weekly for 3 minutes by the dietician (SY) and asked about the total numbers of their color codes over a period of 3 months. In phone calls the participants were asked about the total numbers of colors for food and times of doing physical activities. In every phone call it was recommended that they increase the green colors. Increasing green colors meant consuming low glycemic index food and doing physical activity five days.

Outcome: Fasting blood glucose level was the main outcome for comparison between the intervention and control groups. All laboratory analyses were conducted in the Dokuz Eylul University laboratories.

Statistical analyses: The baseline and 3-month color codes for diet and for physical activity were compared for the intervention group. The intervention and control groups were compared using the chi-square test, for menopausal status, food consumption characteristics and smoking. Mean baseline height, weight, BMI, hip circumference, waist-hip ratio (WHR) and fasting blood glucose levels were also compared for the intervention and control groups using the Mann-Whitney U Test.

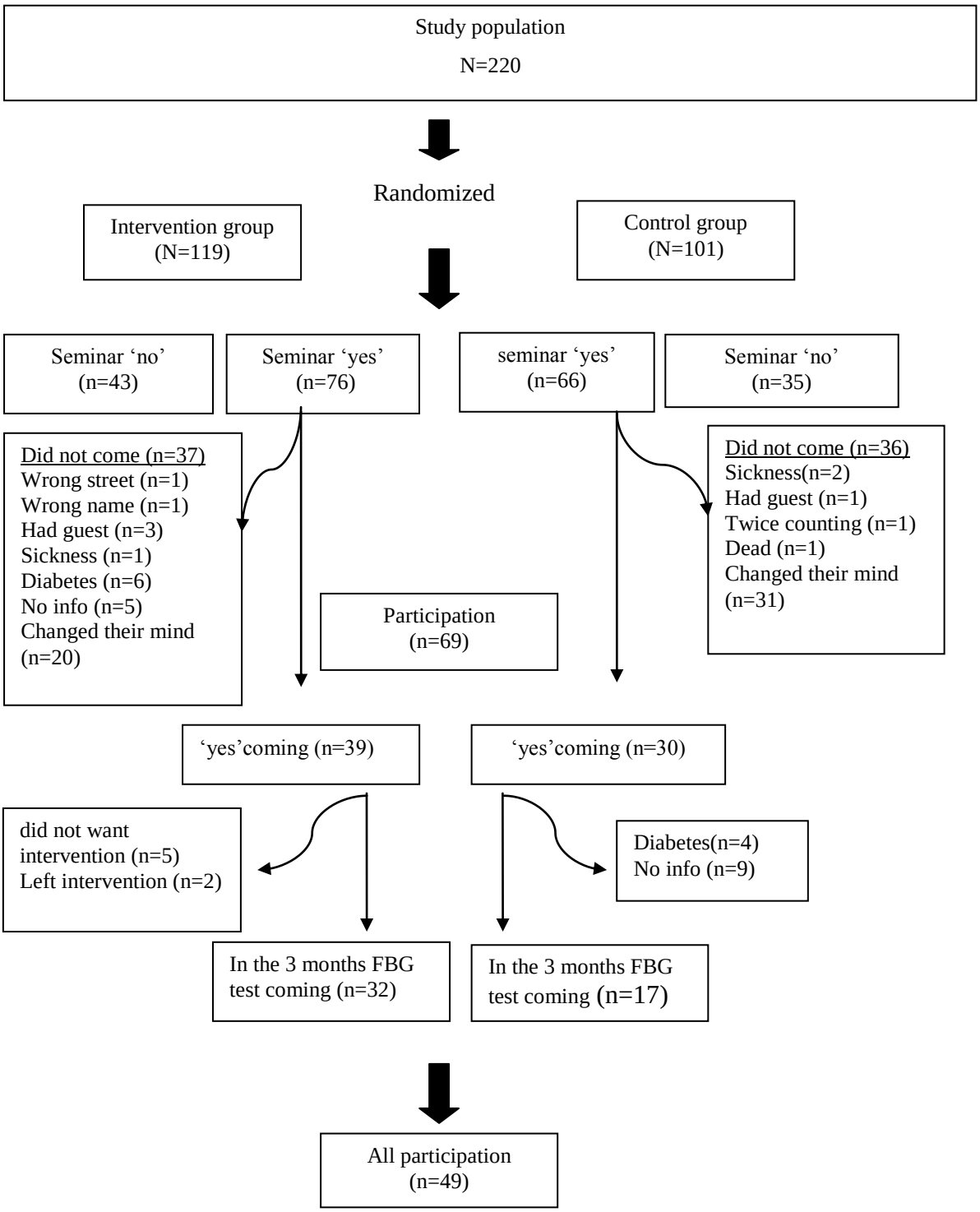

Figure 1 presents the study recruitment and participation flow chart

Activities	None	A week		5 days/a week
		1-2 times	3-4 times	
Walking				
Swimming				
Running				
Cycling				
Doing aerobics				
TOTAL				
Food	everyday/a week	A week		None
		5-6 times	3-4 times	1-2 times
Sugar				
Honey				
White bread				
Offal				
Sesame bagels				
Thin dough				
Pastry				
Corn				
Corn (canned)				
Cornflakes				
Popcorn				
Potato				
Chestnut				
Noodless, pasta, rice (white)				
Dry/fresh fig				
Dry/fresh apricot				
Dry/fresh grapes				
Dry plum				
Banana				
Date				
Melone				
Fruit juice				
Fresh fruit juice				
Margarine, butter				
TOTAL				

Figure 2 Color code charts

In the intervention group, the number of color codes for diet and physical activity at baseline and at 3 months were compared using the dependent groups t test and Wilcoxon Signed Rank Test.

Results

At baseline values of the study, the initial intervention (n=119) and the initial control (n=101) groups were similar regarding age (p=0.81), fasting plasma glucose (p=0.30), BMI (p=0.40), WHR (p=0.40), bread consumption (p=0.29), oil consumption (p=0.61), salt consumption (p=0.44), reading the label of food (p=0.69), vegetable/fruits consumption (p=0.78) and smoking (p=0.22) (Table 1, Table 2)

In total, 32 women in the intervention group and 17 women in the control group attended the last visit.

In these remaining groups, the intervention and control groups were similar regarding age (p=0.66), fasting plasma glucose (p=0.39), BMI (p=0.25), WHR (p=0.64), menopause (p=0.16), smoking (p=0.24), bread consumption (p=0.94), oil consumption (p=0.28), salt consumption (p=0.27), reading the label of food (p=0.86), vegetable/fruits consumption (p=0.33) and smoking (p=0.24) (Table 1a, Table 2a).

Table 1. Anthropometric measurement in the initial intervention and control groups

Characteristics	Intervention group (n=119) mean ±S	Control group (n=101) mean±S	p*
Age	52.2±7.9	52.2±8.5	0.81
Fasting plasma glucose (mg/dl)	107.6 ± 6.8	108.6 ± 7.5	0.30
Height (cm)	156.6±6.6	157.1 ±5.4	0.08
Weight (kg)	78.7 ±11.8	81.4 ±16.1	0.45
BMI(kg/m^2)	32.1 ±4.7	33.0 ±6.4	0.40
Hip(cm.)	111.5±10.1	112.6 ±13.7	0.06
Waist(cm.)	93.7 ±10.4	95.8±13.3	0.68
Waist/hip	0.8± 0.1	0.9 ±0.1	0.40

Table1a. Baseline anthropometric measurements in the intervention and control groups

Characteristics	Intervention group (n=32) mean ±S	Control group (n=17) mean±S	p*
Age	52.5±7.7	51.7±8.4	0.66
Fasting plasma glucose (mg/dl)	107.5 ± 6.9	108.4 ± 7.3	0.39
Height (cm)	156.1±6.2	158.1 ±5.6	0.25
Weight (kg)	79.6 ±10.9	84.4 ±14.5	0.25
BMI(kg/m^2)	32.7 ±4.5	33.8 ±5.8	0.28
Hip(cm.)	112.3±8.3	114.5 ±11.5	0.69
Waist(cm.)	93.8 ±10.1	97.1±8.5	0.19
Waist/hip	0.8± 0.1	0.9 ±0.1	0.64

In the intervention group, the mean number of red color codes for nutrition remained unchanged from 2.1±3.6 at baseline to 2.1±2.5 at 3-months (p=0.41), while the green color codes decreased from 16.2±4.1 at baseline to 15.1±3.7 at 3-months (p=0.03). No significant change was noted in any of the activity color codes (Table 3).

Fasting blood glucose levels were significantly increased in the intervention group at month 3 compared with baseline (107.5±6.9 and 117.0±25.8, p=0.01). However, baseline and 3-month fasting blood glucose levels were not significantly different between the intervention and control groups (p=0.39 and p=0.69 respectively). In the intervention and control groups, delta fasting blood glucose levels were compared. There was not a significantly different (p=0.49) (Table 4).

Discussion

In this study, the effect of regular reminders in telephone calls aimed at motivating the study participants to adopt a healthier diet and engage in physical activity was investigated. At baseline, intervention and control groups were similar regarding age, fasting plasma glucose, BMI, WHR, menopause and dietary behaviors. In the intervention group, a statistically significant reduction was observed in the frequency of green color for foods at the end of three months follow-up from baseline (16.2±4.1 to 15.1±3.7, p=0.03). The frequency of green colors of physical activity did not change from baseline to the 3-month visit. (0.5±0.7 and 0.4±0.7, respectively). The mean fasting blood glucose level was significantly increased in the intervention group (117.0±25.8) compared with the control group (109.5±9.2) at the end of third month follow-up (p=0.04). It was known that the green colors mean represented avoidance of high glycemic index foods and physical activity five days a week. At the end of the study the participants consumed more high glycemic foods and did less physical activity. The mean fasting blood level was significantly increased in the intervention group. One of the explanations can be change in dietary habits with the season. We started the study at end of winter and followed up the intervention group during midsummer. The Turkish diet gets richer with high glycemic index food including grapes and melon during the summer.

In addition, fasting blood glucose can be considered a soft outcome of a telephone call intervention. Because FBG is affected by the state of the participants' daily dietary behaviors rather than the long term blood glucose levels. Measuring HbA1c could be a better indicator for the impact of longer-term interventions.

Development of diabetes is strongly related to lifestyle factors. Previous intervention trials provided evidence that diabetes might be delayed or prevented by physical activity, weight loss and healthier dietary intake, including whole grains, fiber, and dietary fat interventions.[12-14]

Table 2. Dietary behaviors in the initial interventions and control groups

		Intervention		Control		p*
		n	%	n	%	
Bread	White	71	66.4	55	59.1	
	Whole	36	33.6	38	40.9	0.29
Total		107	100	93	100	
Oil	Olive oil	54	50.5	44	46.8	
	Others*	53	49.5	50	53.2	0.61
Total		107	100	94	100	
Salt consumpt.	Yes	10	9.3	12	12.8	
	None	97	90.7	82	87.2	0.44
Total		107	100	94	100	
Reading Label	Yes	37	34.6	30	31.9	
	No	70	65.4	64	68.1	0.69
Total		107	100	94	100	
Vegetable-fruit consumpt.	<5 serving	69	65.7	60	63.8	
	≥5 serving	36	34.3	34	36.2	0.78
Total		105	100	94	100	
Smoking	Ex/current smokers	36	30.5	37	38.5	
	None	82	69.5	59	61.5	0.22
Total		118	100	96	100	

*chi-square test, ** liquid oils except olive oils.

Table 2 a. Dietary behaviors in the interventions and control groups

		Intervention (n=32)		Control (n=17)		p*
		n	%	n	%	
Bread	White	15	51.7	9	52.9	0.94
	Whole	14	48.3	8	47.1	
Oil	Olive oil	15	51.7	6	35.3	0.28
	Others*	14	48.3	11	64.7	
Salt consumpt.	Yes	1	3.4	2	11.8	0.27
	None	28	96.6	15	88.2	
Reading Label	Yes	11	37.9	6	35.3	0.86
	No	18	62.1	11	64.7	
Vegetable-fruit consumpt.	<5 serving	24	82.8	12	70.6	0.33
	≥5 serving	5	17.2	5	29.4	
Smoking	Ex/current smokers	8	25.0	7	41.2	0.24
	None	24	75.0	10	58.8	

*chi-square test. ** liquid oils except olive oils.

Most lifestyle intervention studies have been focused mainly on education, including advice on physical activity and diet, or on exercise training and/or diet. Only a few randomized controlled trials have investigated interventions incorporating several elements of non-pharmacological treatment of type 2 diabetes including patient education, supervised exercise and dietary advice on a

group-basis. It is very important in type 2 diabetes management programs to find ways to increase the impact of non-pharmacological treatments. Our study may add further evidence for this.

One of the earliest lifestyle intervention trials for the prevention of type 2 diabetes was conducted among 370 47-49 year old men in Malmö, Sweden.[15] Men who participated in this lifestyle intervention group (diet and physical activity) revealed a lower incidence of type 2 diabetes. After 12 years of follow-up, men with IGT who received the lifestyle intervention showed no difference in mortality rates when compared with men in the control group, and had less than half the mortality rate when compared to IGT men who received usual care.[12,13,16]

Table 3. Self-rated color codes for food consumption and physical activity in the intervention group (n=32) at baseline and in the third month (mean±S)

Characteristic	At baseline	At 3rd month	p*
Food consumption			
Red color (daily)	2.1 ± 3.6	2.1±2.5	0.41
Yellow color (1-6 times a week)	5.6 ± 3.1	6.8±3.8	0.07
Green color (none)	16.2 ±4.1	15.1±3.7	0.03
Physical activity performance			
Red color (none)	3.5 ±1.2	3.6±1.3	0.60
Yellow color (1-4 times a week)	0.9 ±1.0	0.9±1.1	0.91
Green color (5 times a week)	0.5 ±0.7	0.4±0.7	0.25

The Finnish Diabetes Prevention Study (DPS) was the first randomized controlled trial to specifically examine the effect of a lifestyle intervention in preventing type 2 diabetes.[17,18] In this study 522 overweight/obese subjects with IGT were randomized to either a lifestyle intervention or a control group. The lifestyle intervention provided individualized diet and exercise counseling focused on achieving and maintaining healthy body weight, reducing total intake of fat and saturated fat, and increasing fiber intake and physical activity. After an average of 3.2 years follow-up, there was a 58% reduction in the incidence of diabetes in the intervention group compared with the control group. Similar findings were shown also in a developing country context. The Da Qing Study examined the effect of a 6-year diet and exercise intervention in Chinese subjects with IGT (mean age=45). The diet intervention alone was associated with a 31% reduction, at the same time whereas the exercise intervention alone showed a 46% reduction, and the combined diet and exercise group had a similar 42% reduction in the risk of developing type 2 diabetes during a 6-year follow-up period.[19] In these early studies, interventions for nutrition were based on a dietician's calorie diet plans specific to the individuals. In our study, we provided healthy eating messages through reminder charts rather than offering calorie plans. Reminder charts were developed for this study and used in the field for the first time in Turkey. The charts were thought to be a useful, understandable and applicable tool to spread healthy eating messages. This type of patient reminder tool can be practical for healthy people in the field too.

Patient compliance with the intervention is crucial in these trials. In our study, we made regular phone calls both as reminders of the interventions and to improve compliance.

Table 4. Mean fasting blood glucose level (FBG) in the intervention and control groups at baseline and third month

Characteristic	Group Intervention (n=32) mean ±S	Control(n=17) mean ±S	p*
Baseline FBG	107.5 ± 6.9	108.4 ± 7.3	0.39
Third month FBG	117.0 ± 25.8	109.5 ± 9.2	0.69
DeltaFBG	9.06±23.59 (6.0)#	3.24±7.60 (4.0)#	0.49
p**	0.01	0.08	-

* Mann-Whitney U test, ** Wilcoxon signed ranks test, # Median

Our study is one of the first national studies that intended to increase healthy nutrition and performance of physical activity through regular phone reminders to people with high diabetes risk in the community. Performing community-based interventional trials presents a number of challenges. Firstly, the study group of the current study comprised healthy women with impaired fasting glucose rather than diabetes patients. This condition might limit individual's motivation to participate and remain in the study. People with impaired fasting glucose should receive individualized medical nutrition treatment (MNT) as needed to achieve treatment goals based on their health status, dietary preferences, and cultural backgrounds. Secondly, the two neighborhoods included in the study may be considered to be of low and middle socio-economic status. The majority of women who participated in the study were housewives and their decision and commitment to participate and stay in the study might be influenced by many external conditions including husbands' attitudes, heavy housework duties and responsibilities. Thirdly, as the study was conducted between May and September, the number of individuals participating in the study follow-up might have decreased due to summer holidays. To overcome these potential limitations we randomized more women than we needed. However due to high loss to follow-up the power of the study further decreased. Low numbers of participants in both intervention and control groups might reduce the ability of our study to detect a real difference between the intervention and control groups for our trial.

Despite the possible limitations, our study was the first intervention study in the Balçova Heart Project and showed the need for further multidisciplinary studies for determining effective life style change interventions in high risk people in a Turkish urban population. Multidisciplinary teams should include more dieticians, nurses, community health workers that may facilitate community-wide education campaigns and community participation. For example, through working together, communities may develop a greater sense of cohesion and collective self-efficacy. Social networks may also be developed or strengthened to achieve intervention goals, and community members may become involved in local government and civil organizations.

Conclusion

In our study, regular reminder phone calls alone were not sufficient for lowering fasting blood glucose level and enhancing the performance of regular physical activity. However results should be interpreted cautiously because of high loss during follow-up. There is a need for studies that evaluate different and new lifestyle change interventions in high risk people in Turkey.

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The study is prepared with 41/2008 protocol number. All the research meets the ethical guidelines, including adherence to the legal requirements of the study country.

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