Color record in self-monitoring of blood glucose improves glycemic control by better self-management

（カラー記録を活用した血糖自己測定は自己管理行動と血糖コントロールの改善に寄与する）

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SHORT RUNNING TITLE: SMBG COLOR RECORD IMPROVES GLYCEMIC CONTROL

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Abstract

Background: Color affects emotions, feelings and behaviors. We hypothesized that color used in self-monitoring of blood glucose (SMBG) is helpful for patients to recognize and act on their glucose levels to improve glycemic control. Here, two color-indication methods, color record (CR) and color display (CD), were independently compared for their effects on glycemic control in less frequently insulin-treated type 2 diabetes.

Methods: One hundred twenty outpatients were randomly allocated to 4 groups with two-by-two factorial design; CR or non-CR, and CD or non-CD. Blood glucose levels were recorded in red or blue pencil in CR arm and a red or blue indicator light on the SMBG meter was lit in CD arm, under hyperglycemia or hypoglycemia, respectively. The primary endpoint was difference in HbA1c reduction in 24-week. Secondary endpoints were self-management performance change and psychological state change.

Results: HbA1c levels at 24-week were significantly decreased in CR arm by -0.28%, but were increased by 0.03% in non-CR arm (p=0.044). In addition, diet and exercise scores were significantly improved in CR arm compared to non-CR arm. Exercise score showed significant improvement in CD arm compared with non-CD arm, but without a significant difference in HbA1c reduction. Changes in psychological states were not altered between the arms.

Conclusions: CR has a favorable effect on self-management performance without any influence on psychological stress, resulting in improved glycemic control in type 2 diabetes patients using less frequent insulin injection. Thus, active but not passive usage of color-indication methods by patients is important in successful SMBG.

Background

Self-monitoring of blood glucose (SMBG) provides an instrument for objective feedback on the impact of daily lifestyle habits, health conditions (e.g., illness, stress), and medications on glucose levels. It fosters self-management and empowers individuals to make beneficial changes in lifestyle. The American Diabetes Association (ADA) recommends that SMBG be included in diabetes management and glycemic control for patients on multiple-dose insulin[1]. On the other hand, there is no consensus on the utility of SMBG for glycemic control in diabetes patients using less frequent insulin injection because of controversial evidence from previous reviews[2-4].

It is unclear why SMBG has no distinct effect on glycemic control for type 2 diabetes patients with less frequent insulin injection. However, a higher frequency of SMBG tests is associated with improved glycemic control in patients with type 1 diabetes[5] and also with type 2 diabetes[6]. The low frequency of SMBG tests in patients using less frequent insulin injection might be a factor in the observed lack of improved glycemic control. SMBG is more helpful in diabetes management and glycemic control in conjunction with comprehensive self-care education, skills training, and ongoing support for patients[4, 7]. However, many patients, especially those with less frequent SMBG, take no action when their SMBG meter displays hyperglycemia or hypoglycemia[8]. The unmet need of SMBG is to find a simpler, more efficient, and more economical method of promoting improvement in self-management and glycemic control.

To address this issue, we compared two separate color-indication methods: color record (CR) and color display (CD), both of which add color to emphasize high or low blood glucose levels in SMBG. Color is known to directly affect emotions, feelings and behaviors in humans. It motivates different cognitive learnings: red produces avoidance motivation and enhances detail-oriented task; blue produces approach motivation and enhances creative task[9, 10]. We show here that color record has a favorable effect on self-management performance without any influence on psychological stress, resulting in improved glycemic control mostly due to an increase in motivation for exercise and diet.

Research Design and Methods

Participants

This study, called the Color IMPACT study (Color in SMBG Improves self-management Performance by Approaching Cognitive Transmission), is a prospective, randomized, controlled, single center, open trial with a two-by-two factorial design to evaluate the effect of two color-indication methods used in SMBG, color record (CR) and color display (CD), on glycemic control in type 2 diabetes patients. Outpatients of Kyoto University Hospital were recruited. Inclusion criteria were: type 2 diabetes with insulins; ongoing SMBG; aged between

20 and 80 years old; HbA1c levels between 7.0 and 10.5%; and ability to diet and/or exercise. Exclusion criteria were: diabetes duration < 1 year; initiation or treatment change with insulin or GLP-1 receptor agonists within 4 months; SMBG operated by other persons; severe comorbidities (e.g., severe cardiovascular disease, liver and renal disorders, malignancy); depression or psychiatric problems; impaired vision or synesthesia; abnormal hemoglobinemia; pregnancy; inability to follow trial procedures; or patients unsuitable for this study as judged by physicians. The study protocol was approved by the Institutional Review Board of Kyoto University Hospital (E1332) and is in compliance with the Helsinki Declaration. Written informed consent was obtained from all subjects.

Procedures

The study duration was 24 weeks. The subjects were assigned according to a two-by-two factorial design to one of four groups (Figure 1): (A) no color display and no color record group, (B) no color display and color record group, (C) color display and no color record group, and (D) color display and color record group with a randomly generated allocation code using balanced design (age, gender, HbA1c, diabetes duration, and the number of SMBG tests) in consecutively numbered sealed envelopes.

All of the subjects visited the hospital every 4 weeks, and laboratory data including HbA1c, frequency of SMBG tests, and all documented medications were collected at 0, 4, 12, and 24 weeks. Subjects completed a questionnaire on self-management performance and psychological states at 0, 4, 12, and 24 weeks. Physicians-in-charge also filled in an original questionnaire about SMBG at 0 and 24 weeks.

Six diabetologists and three certified diabetes nurses participated in the study; the concepts and methods of the study were all learned in the same manner by all participants.

Intervention

All subjects were newly provided with a blood glucose meter (One touch® Ultra Vue™; Johnson & Johnson K.K., Japan), and instructed by one of the three nurses at enrollment. The subjects were requested to use the meter and record blood glucose levels manually in self-monitoring notes during the study.

One touch® Ultra Vue™ emphasizes blood glucose levels with 5-color indicator lights (red, orange, green, light blue, and blue), which appear in a rectangle shape (4.5 mm tall × 14.5 mm wide) under blood glucose value in black numbers (14 mm tall × 6-10 mm wide) on a display screen (42 mm tall × 33 mm wide) with white background for 180 seconds. In group C and group D, red, orange, green, light blue, and blue is shown when blood glucose levels are 8.9 mmol/l (160 mg/dl) or greater, 7.3-8.8 mmol/l (131-159 mg/dl), 5.0-7.2 mmol/l (90-130 mg/dl), 3.9-4.9 mmol/l (71-89 mg/dl), and less than 3.8 mmol/l (70 mg/dl), respectively (color display

(CD) arm) (Figure 1). However, the indicator lights were turned off and blood glucose levels were shown just in black on the meter for group A and group B (no color display (non-CD) arm).

Self-monitoring notes are provided by the Japan Association for Diabetes Education and Care (JADEC), and commonly used by patients to record blood glucose levels in Japan. In the study, subjects in group A and group C recorded their blood glucose levels on the note manually in black pencil (no color record (non-CR) arm). Group B and group D recorded their blood glucose levels in black and marked them with red or blue pencils when their glucose levels were 8.9 mmol/l (160 mg/dl) or greater, or less than 3.8 mmol/l (70 mg/dl), respectively (color record (CR) arm) (Figure 1).

Measurements

The primary endpoint was difference in HbA1c reduction in 24-week between CR (B+D) and non-CR (A+C) arms, and CD (C+D) and non-CD (A+B) arms. The secondary endpoints were differences in self-management performance change and psychological state change, and difference in HbA1c reduction in 24-week in treatment-unchanged subjects. Self-management performance was evaluated by The Summary of Diabetes Self-Care Activities Measure (SDSCA)[11]. The higher mean scores by subscales indicate the higher level of each self-care practice. Psychological states were measured using a validated, abridged version of Profile of Mood States (POMS)[12]. SDSCA was used to determine the effect of color on self-management performance, and POMS was performed because SMBG is reported to be associated with depression[13]. We also examined physician`s attitude to SMBG because lack of physicians' interest in the results of SMBG decreases motivation of patients[14]. The original physician questionnaire consisted of 4 closed questions with a five-point Likert scale from 0 (“not at all”) to 4 (“extremely”): physician’s satisfaction with the physician-patient relationship; sharing a common goal for glycemic control with patients; usefulness of SMBG for physicians in glycemic control; and usefulness of SMBG for patients in glycemic control. All questionnaires were administered by certified diabetes nurses.

Statistical analysis

To examine the primary endpoint, independent sample Student’s t-test was used. Dependent samples Student’s t-test was used to compare the means of HbA1c levels between baseline and 24 weeks in CR, non-CR, CD, and non-CD arms. Similarly, independent sample Student’s t-test was used to compare the change in the score on diet subscale of the SDSCA, the change in the score on all subscales of the POMS, and the change in HbA1c levels in 24-week in treatment-unchanged subjects. Mann-Whitney non-parametric u-test was applied to compare change in the score on exercise and medications subscales of the SDSCA, since these variables were not normally distributed. X-square test was used to compare ratio of patients with improvements in the physician's questionnaire in 24-week. *P* values < 0.05 were considered as statistically significant.

Results

Subjects

One hundred twenty subjects were enrolled in the study and randomized to 4 groups: group A, 31; group B, 27; group C, 29; and, group D, 33. These 4 groups were structured for the factorial design: a non-CR arm consisting of groups A and C; a CR arm consisting of groups B and D; a non-CD arm consisting of groups A and B; and a CD arm consisting of groups C and D (Figure 1). The mean age (mean ± SD) was 66.8 ± 9.9 years old, 40.6% of the subjects were female, the diabetes duration was 17.7 ± 9.3 years, the mean HbA1c level was 7.88 ± 0.85%, the SMBG frequency was 2.04 ± 0.95 times / day, and the frequency of insulin injection was 2.16 ± 1.09 times / day. There was no significant difference in demographic data of the subjects at the baseline among the 4 arms (Table 1). No significant differences were found in the socioeconomic status or levels of education between arms (data not shown). One hundred one of 120 subjects (84.2%) completed the study. Nine subjects (15.0%) in non-CR, 10 (16.7%) in CR, 9 (15.5%) in non-CD, and 10 (16.1%) in CD arms were dropped because of hospitalization for diabetes and comorbidities with no significant difference among the arms.

HbA1c findings

HbA1c levels (mean ± SE) were significantly decreased in CR arm by -0.28 ± 0.12% (7.92 ± 0.12% to 7.64 ± 0.15%, $p = 0.018$), but were increased by +0.03 ± 0.10% in non-CR arm (7.84 ± 0.12% to 7.87 ± 0.16%, $p = 0.783$) in 24-week (Figure 2A and 2C). Difference in change in HbA1c levels in 24-week between CR and non-CR arms was -0.31% (95% CI, -0.61 to -0.01) with a significant difference of p=0.044. On the other hand, HbA1c levels were not significantly decreased, from 7.95 ± 0.12% to 7.81 ± 0.16% ($p = 0.191$) in CD arm and from 7.81 ± 0.12% to 7.70 ± 0.15% ($p = 0.334$) in non-CD arm in 24-week (Figure 2B). Change in HbA1c in 24-week was -0.14 ± 0.10% in CD arm and -0.11 ± 0.12% in non-CD arm with no significant difference ($p = 0.866$) between the arms (-0.03%, 95% confidence interval (95% CI) -0.33 to 0.28) (Figure 2D). Correlation between change in HbA1c and the number of SMBG tests (times/day) was not found in CR arm (Pearson's product-moment correlation coefficient = -0.050, $p = 0.728$) (data not shown). The other factors such as age, sex, socioeconomic status, and education levels did not affect the difference in change in HbA1c between CR and non-CR, or CD and non-CD arms.

Treatment-unchanged subjects also were analyzed for the effect of color on glycemic control. In these subjects, a significant change in HbA1c at 24-week was observed in CR arm compared to that in non-CR arm (-0.31 ± 0.13%, $p = 0.021$ vs. +0.04 ± 0.11%, $p = 0.715$) (Figure 2E). The difference in change in HbA1c between CR and non-CR arms was -0.35% (95% CI -0.69 to -0.02, $p = 0.038$). On the other hand, change in HbA1c in 24-week were -0.28 ± 0.13% in CD arm ($p = 0.037$) and 0.00 ± 0.11% in non-CD arm ($p = 0.981$) (Figure 2F). The apparent difference in change in HbA1c between the arms was not significant (-0.28%, 95% CI -0.62 to 0.06, $p = 0.106$).

Self-management performance

There were no statistically significant differences in the baseline scores on diet, exercise, and medication subscales of the SDSCA between CR and non-CR arms, and between CD and non-CD arms (Table 2). Scores on diet and exercise subscales of SDSCA in 24-week were significantly increased in CR arm compared to those in non-CR arm. Change in diet subscale score (mean ± SE) was +0.21 ± 0.15 points in CR arm and -0.23 ± 0.16 points in non-CR arm. The difference in change in diet scores between CR and non-CR arms was +0.44 points (95% CI +0.01 to +0.87, $p = 0.043$). Median change in exercise subscale score in 24-week was +0.50 (interquartile range (IQR) -1.00 to +1.00) points in CR arm and 0.00 (IQR -1.00 to +1.00) points in non-CR arm with a significant difference between the arms ($p = 0.045$).

Median change in the score on exercise subscale in 24-week was +0.50 (IQR -0.50 to +1.00) points in CD arm and ±0.00 (IQR -2.00 to +0.50) points in non-CD arm. The difference between the arms was statistically significant ($p = 0.045$), but there were no significant differences in change in the scores of diet ($p = 0.696$) and medication subscales ($p = 0.095$) between arms. Change in medication subscale score was similar between each of the two arms (CD vs. non-CD, $p = 0.095$, CR vs. non-CR, $p = 0.095$) (Table 2).

Psychological states

The baseline scores on all subscales of POMS in each arm were within normal range. There were no significant differences in all subscale scores at baseline and at 24 weeks between CR and non-CR arms, and between CD and non-CD arms (data not shown).

Physician's perspectives on SMBG

There were no significant differences in all questions between each of the two arms at baseline (Table 2). With regard to question No. 2 (sharing a common goal for glycemic control with patients), the scores were improved at 24 weeks from baseline by 26.0% in CR arm and by 9.8% in non-CR arm with a significant difference between the arms ($p = 0.033$). However, a significant difference was not found between CD arm (15.4%) and non-CD arm (20.4%) ($p = 0.510$) (Table 2). There were no significant differences in the other three questions at 24 weeks between the two arms.

Discussion

The goal of the present study was to ascertain whether or not two color-indication methods used in SMBG, color record (CR) and color display (CD), improved glycemic control through an increase in self-management performance in less frequently insulin-treated type 2 diabetes patients. We hypothesized that color indication methods might motivate patients to recognize hyperglycemia and hypoglycemia and to begin problem-solving behavior. However, only CR has a favorable effect on glycemic control, through motivation to diet and exercise.

Correlation of change in HbA1c and number of SMBG tests was not found in CR arm. In addition, the number of SMBG tests was similar between CR and CD arms. It is important in SMBG usage not to merely check blood glucose levels more frequently but to take action on the findings. Recording their blood glucose levels in blue or red can facilitate patients' change of behavior, as motivation to diet and exercise was increased during the study. On the other hand, although motivation to exercise was increased, glycemic control was not improved in CD arm. Even though hyperglycemia and hypoglycemia are emphasized on the SMBG meter in CD arm, the information did not always cause behavioral changes. These results suggest that active but not passive usage is important in successful SMBG.

Action by patients is a key to improve glycemic control in type 2 diabetes treated less frequently with insulin injection. SMBG is recognized as one tool for such self-management. However, it has been reported that many patients often do nothing when blood glucose levels are high or low when using the existing non-color method of SMBG[8]. Furthermore, lack of physicians' interest in the results of SMBG decreases motivation of patients[14]. However, in our study, sharing a common goal for glycemic control was increased in CR arm compared to non-CR arm, indicating that CR in SMBG can be beneficial in promoting mutual understanding and partnership between patients and HCPs. As a result, self-management performance and HbA1c levels were improved in CR arm not only of all subjects but also of treatment-unchanged subjects.

Change in psychological states was not observed in either arm of the present study. The ESMON study showed that SMBG was associated with higher scores on depression when newly diagnosed diabetes patients were reviewed by HCPs at a long-term (3 months) interval[13]. On the other hand, SMBG with adjuvant counseling at 0, 4, 12 and 20 weeks resulted in improvements on general well-being and depression[15]. In our study, all subjects were reviewed by nurses at 0, 4, 12, and 24 weeks in addition to regular monthly assessment by physicians. All subjects were free to ask the nurse's advice at any time. Reassurance is a key for continued self-monitoring[14]. Subjects in our study showed a sense of reassurance, and were not distressed by poor results of SMBG.

The potential weakness of this study is that this was single center trial, and that the sample size is too small to determine whether the combination of CR and CD is more effective for glycemic control than CR alone. However, subanaysis suggested that CR alone has a more favorable effect on glycemic control compared to combination of CR and CD (data not shown), implying that too much information for patients may not necessarily improve motivation to lifestyle modification and glycemic control. Further studies are needed to clarify which patients are more likely to benefit from CR, CD, and other methods of SMBG.

In summary, CR has a favorable effect on self-management performance without any influence on psychological stress, and results in improved glycemic control in less frequently insulin-treated type 2 diabetes patients. Our results indicate that providing medical care and educational aid are not always helpful for self-management; however, this might not be limited to SMBG usage. Maintenance of a balance of intervention between patients and HCPs is important for optimized self-management.

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Auther Disclosure Statement

No competing financial interests exist.

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TABLE 1. DEMOGRAPHIC OF SUBJECTS AT THE BASELINE

Variables	*CR* *n = 60*	*Non-CR* *n = 60*	*p value*	*CD* *n = 62*	*Non-CD* *n = 58*	*p value*
Age (years)	67.9 ± 9.2	66.0 ± 1.4	0.303	66.4 ± 9.8	67.5 ± 10.7	0.572
Female (%)	41.7	40.0	0.853	43.5	37.9	0.532
Diabetes duration (years)	17.0 ± 8.7	17.0 ± 9.9	0.984	17.9 ± 10.2	16.0 ± 8.1	0.280
HbA1c (%)	7.87 ± 0.81	7.99 ± 1.10	0.521	7.97 ± 0.99	7.89 ± 0.93	0.658
SMBG frequency (times / day)	2.28 ± 1.21	1.92 ± 0.77	0.059	2.21 ± 1.16	1.98 ± 0.85	0.227

Data are means ± SD. CR, color record; CD, color display; SMBG, self-monitoring of blood glucose.

TABLE 2. THE SCORES OF THE SDSCA QUESTIONNAIRE AND CHANGE IN THE SCORE OF PHYSICIAN'S QUESTIONNAIRE IN 24-WEEK

Variables	*CR* *n = 51*	*Non-CR* *n = 50*	*p*	*CD* *n = 49*	*Non-CD* *n = 52*	*P*
SDSCA						
Diet						
Baseline	4.10 ± 0.23	4.32 ± 0.18	0.457	4.25 ± 0.21	4.18 ± 0.20	0.799
At 24 weeks	4.32 ± 0.20	4.09 ± 0.17	0.393	4.20 ± 0.19	4.21 ± 0.18	0.964
Change in score	+0.21 ± 0.15	-0.23 ± 0.16	0.043*	-0.05 ± 0.15	-0.03 ± 0.16	0.696
Exercise						
Baseline	2.75 (2.88)	4.00 (3.50)	0.097	2.75 (2.88)	4.00 (3.25)	0.062
At 24 weeks	3.00 (3.63)	3.50 (3.50)	0.138	3.00 (3.38)	3.50 (3.00)	0.688
Change in score	+0.50 (2.00)	±0.00 (2.00)	0.045*	+0.50 (1.50)	±0.00 (2.50)	0.045*
Medication						
Baseline	7.00 (0.00)	7.00 (0.00)	0.058	7.00 (0.00)	7.00 (0.00)	0.723
At 24 weeks	7.00 (0.00)	7.00 (0.00)	0.436	7.00 (0.00)	7.00 (0.00)	0.379
Change in score	±0.00 (0.00)	±0.00 (0.00)	0.095	±0.00 (0.00)	±0.00 (0.00)	0.095
Physician's Questionnaire						
No. 1 Physician satisfaction?			0.215			0.689
Increase	14 (28.0)	9 (17.6)		11 (21.2)	12 (24.5)	
Not increase	36 (72.0)	42 (82.4)		41 (78.8)	37 (75.5)	
No. 2 Shared goal?			0.033*			0.510
Increase	13 (26.0)	5 (9.8)		8 (15.4)	10 (20.4)	
Not increase	37 (74.0)	46 (90.2)		44 (84.6)	39 (79.6)	
No. 3 Usefulness for physician?			0.231			0.203
Increase	9 (18.0)	5 (9.8)		5 (9.6)	9 (18.4)	
Not increase	41 (82.0)	46 (90.2)		47 (90.4)	40 (81.6)	
No. 4 Usefulness for patient?			0.778			0.674
Increase	17 (34.0)	16 (31.4)		16 (30.8)	17 (34.7)	
Not increase	33 (66.0)	35 (68.6)		36 (69.2)	32 (65.3)	

Diet data are means ± SE. Exercise and medication data are median (interquartile range). Values in physician's questionnaire are number (percentages). *$p < 0.05$. Question No. 1, Physician's satisfaction with the physician-patient relationship; Question No. 2, Sharing a common goal for glycemic control with patients; Question No. 3, Usefulness of SMBG for physician in glycemic control; Question No. 4, Usefulness of SMBG for patient in glycemic control. SDSCA, Summary of Daibetes Self-Care Activities Measure; CR, color record; CD, color display; SMBG, self-monitoring of blood glucose.

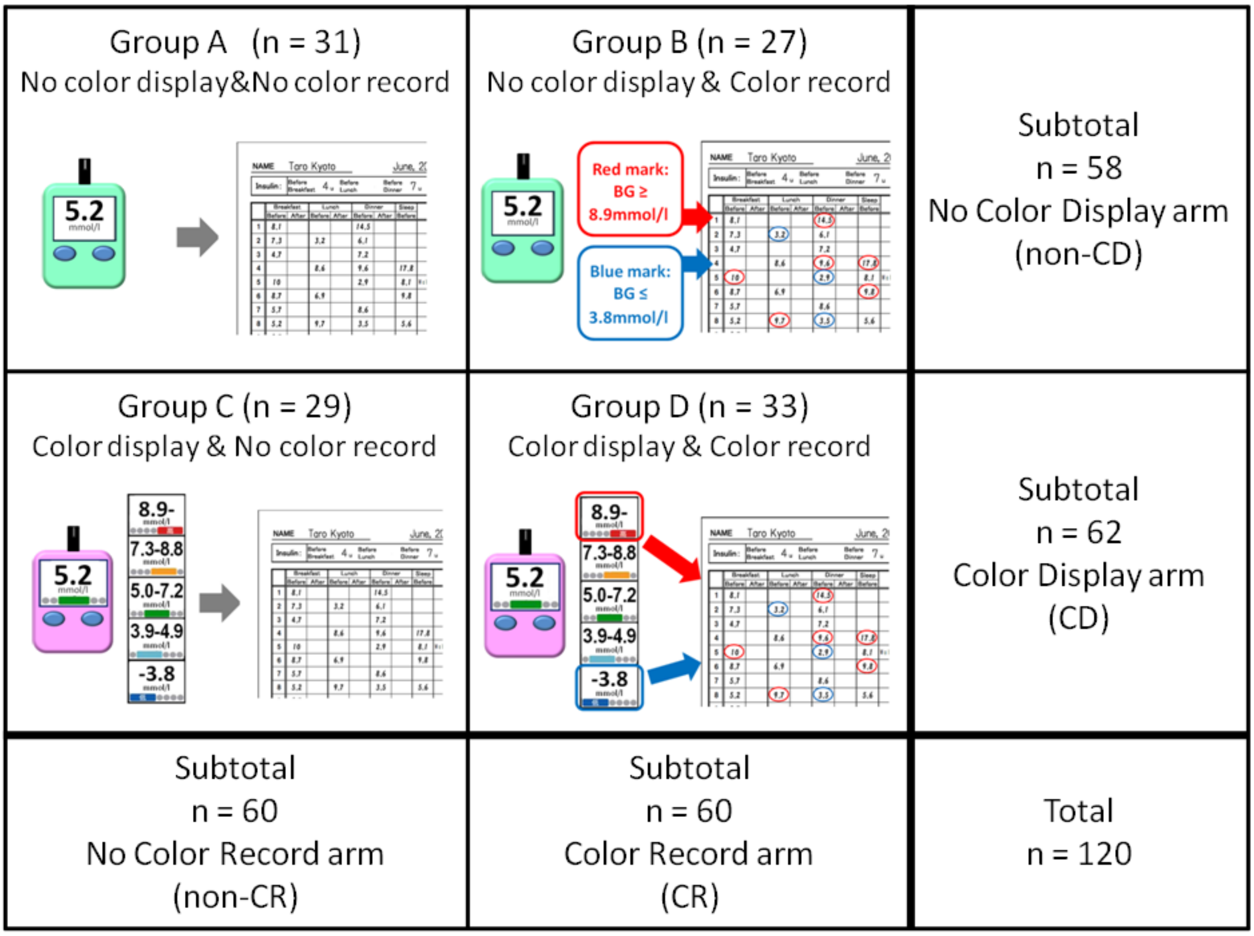

FIGURE 1. Two-by-two factorial design and the number of subjects in each group and arm.

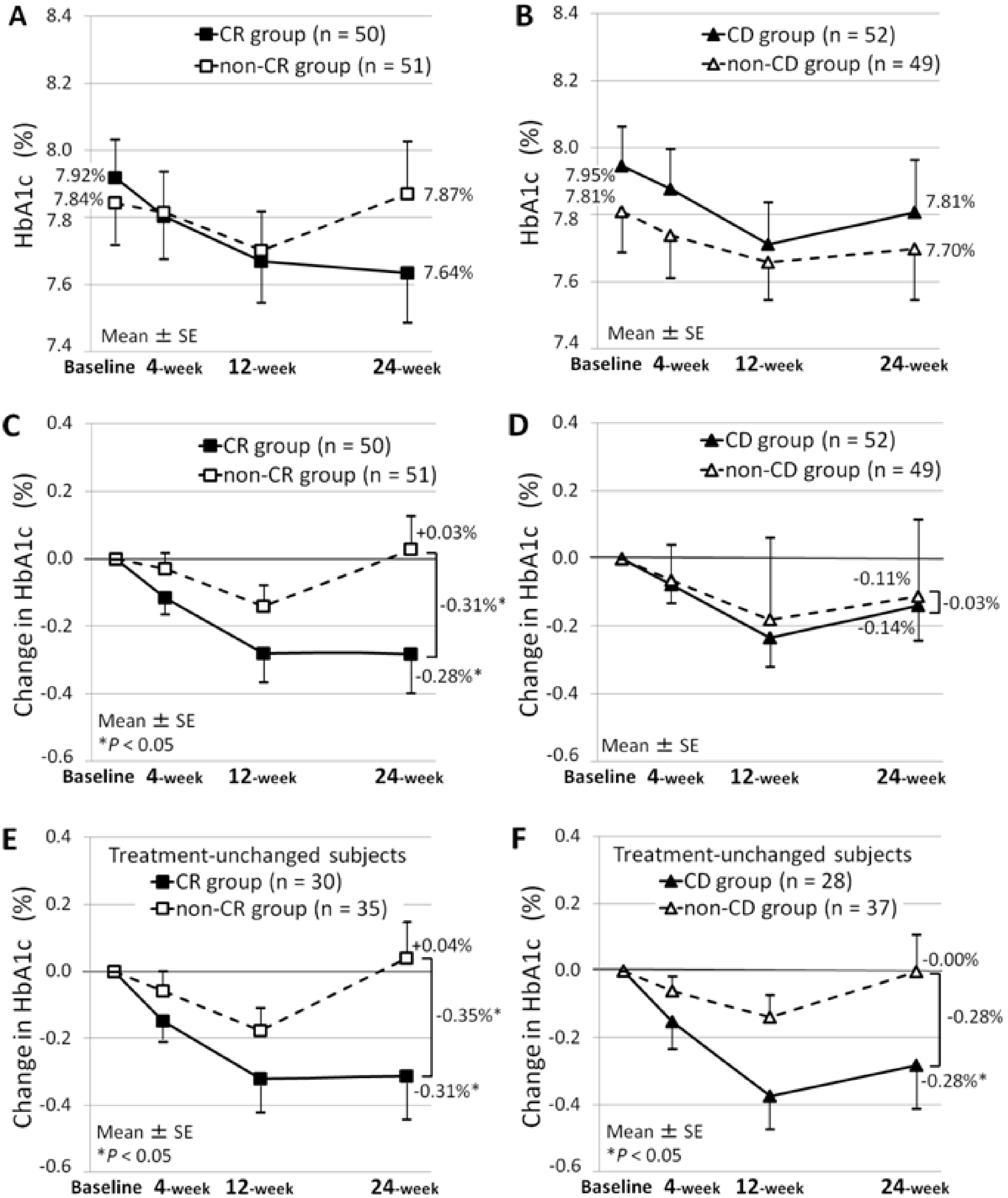

FIGURE 2. HbA1c levels during the study. A and B: HbA1c levels during a 24-week study period in CR and non-CR arms (A), and CD and non-CD arms (B). C and D: Change in HbA1c level during a 24-week study period in CR and non-CR arms (C), and CD and non-CD arms (D). E and F: Change in HbA1c level in the treatment-unchanged patients during a 24-week study period in CR and non-CR arms (E), and CD and non-CD arms (F). CR, color record; CD, color display.