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ORIGINAL RESEARCH

Long-Term Effect of the Color Record Method in Self-Monitoring of Blood Glucose on Metabolic Parameters in Type 2 Diabetes: A 2-Year Follow-up of the Color IMPACT Study

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ABSTRACT

Introduction: This article evaluates the potential long-term effect of two different color indication methods for self-monitoring of blood glucose (SMBG), the color record (CR) and color display (CD), on metabolic parameters in insulin-treated type 2 diabetes in a post-intervention period.
Methods: 101 participants with type 2 diabetes who completed the Color IMPACT study were enrolled in a 2-year comparison follow-up study. Participants continued SMBG with their usual diabetes care. The study outcomes were differences in change in HbA1c levels, blood pressure (BP), body weight and lipid profiles between the CR and non-CR arms and the CD and non-CD arms during a 1- and 2-year period of the study.
Results: 98 participants were analyzed. Reductions in HbA1c levels, systolic BP and low-density lipoprotein cholesterol levels were maintained in the CR arm by − 0.40% (95% CI: − 0.73 to − 0.06, $p = 0.020$), −1 3.2 mmHg (95% CI: − 24.1 to − 2.3, $p = 0.019$), − 11.4 mg/dl (95% CI: − 18.1 to − 4.6, $p = 0.001$), respectively, in a 1-year period. However, HbA1c and BP returned to the baseline levels during an additional 1-year period. In contrast, there were no significant changes in outcome in the CD arm during the study period.
Conclusion: Intervention promoting self-action such as the color record method in SMBG sustains a beneficial effect on metabolic parameters after the intervention. This long-term effect is helpful for people with type 2 diabetes to manage their diabetes ABCs (HbA1c, BP, cholesterol) and to prevent diabetic complications.
Trial Registration: UMIN clinical trials registry identifier, UMIN000006865.

Keywords: Color record; Metabolic parameter; Self-monitoring of blood glucose; Type 2 diabetes

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INTRODUCTION

The main aim of diabetes treatment is to prevent the development of diabetic complications and to inhibit their progress. For that purpose, it is important not only to control blood glucose levels, but also to control the blood pressure (BP), lipid profile, and body weight [1]. The American Diabetes Association recommends that most people with diabetes achieve a glycated hemoglobin (HbA1c) < 7.0% and BP < 140/90 mmHg. In addition, statin therapy is recommended for people with diabetes with atherosclerotic cardiovascular disease risk factors including low-density lipoprotein cholesterol (LDL-C) ≥ 100 mg/dl [2]. However, it is reported that simultaneous attainment of the three goals was 10–30% in both Western [3–5] and Asian countries [6–9].

Pharmacotherapy is important to achieve the three goals of diabetes ABCs (HbA1c, BP, cholesterol), but self-management by people with diabetes themselves is also important. In particular, self-monitoring of blood glucose (SMBG) is the most useful method for their daily diabetes management [10, 11]. Frequent SMBG use in both insulin-treated and insulin-naïve people with diabetes is known to contribute at least some improvement in glycemic control [12, 13] as well as savings of overall healthcare costs because of the reduced number and duration of hospitalizations [14]. On the other hand, less frequent SMBG also improves glycemic control and diabetes management [15–18]. In general, the frequency of SMBG must be reevaluated at each routine visit to avoid excessive use in people with diabetes using less frequent insulin injection and non-insulin therapies [2, 19].

We have previously reported the effect of two different color indication methods used in SMBG, the color record (CR) and color display (CD), on glycemic control and self-management performance in people with type 2 diabetes using less frequent insulin injections (the Color IMPACT study) [20]. In that study, hyper- and hypoglycemia were emphasized by color on the record written by people with diabetes in the CR arm and on the display of the SMBG meter in the CD arm. The study demonstrated that CR in SMBG has a beneficial effect on glycemic control and self-management performance of diet and exercise in 24 weeks without any influence on psychologic stress.

However, it is not clear how long such a self-motivated intervention in SMBG should be carried out or how long the desired behavior changes might be sustained after intervention. We thus evaluated the sustained effect of the two color indication methods used in SMBG on diabetes management in a follow-up of the Color IMPACT study. We show here that in the SMBG method CR but not CD can sustain the beneficial effect on metabolic parameters for the post-intervention time period.

METHODS

Study Design

Details of the study protocol, participants, and methods for the Color IMPACT study were reported previously (Clinical registration number: UMIN000006865, UMIN Clinical Trials Registry: http://www.umin.ac.jp/ctr/index.htm) [20]. Briefly, the Color IMPACT study was a 24-week, prospective, randomized controlled trial with a 2 × 2 factorial design to evaluate the effect of two color indication methods used in SMBG, CR, and CD on glycemic control in people with type 2 diabetes (Figure S1). Blood glucose levels were recorded in red or blue pencil manually in a record by the participants in the CR arm and by a red or blue indicator light on the SMBG meter in the CD arm, representing hyperglycemia (glucose level ≥ 160 mg/dl) and hypoglycemia (glucose level < 70 mg/dl), respectively.

The present study was a 2-year follow-up of the Color IMPACT study. Participants who completed the Color IMPACT study continuously received insulin therapy and hospital-based diabetes care according to their clinical needs and continued SMBG use with no attempt to maintain previously randomized SMBG methods. No intervention by researchers was conducted during the follow-up period.

All procedures performed in the follow-up study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent for this follow-up study was exempted by the Institutional Review Board (IRB) because written informed consent had been obtained from all individual participants in the Color IMPACT study. The protocol for the follow-up study was approved by the IRB of Kyoto University Hospital (R0886).

Participants

In the Color IMPACT study, 120 subjects with type 2 diabetes were enrolled in the clinical setting and randomly assigned to one of four groups (group A–D, 1:1:1:1 ratio). Then, four arms (CR, non-CR, CD, non-CD) were structured by four groups (group A–D) for the factorial design (Figure S1). Of these participants, the 101 participants who completed the Color IMPACT study [20] were registered into the follow-up study: 50 participants (83.3%) in the CR arm, 51 (85%) in the non-CR arm, 52 (83.9%) in the CD arm, and 49 (84.5%) in the non-CD arm. The enrollment ratio did not differ between the CR and non-CR arms and the CD and non-CD arms (Fig. 1).

End points

The primary end point was change in HbA1c levels in 52- and 104-weeks from the baseline of the Color IMPACT study. The secondary end points were change in systolic BP (SBP), diastolic BP (DBP), body weight (BW), and LDL-C levels at 52 and at 104 weeks. End point examinations were performed at the time of the subjects' visits to their primary physicians. All data were collected from medical records blindly by trained staff.

Statistical Analysis

Data were expressed as means and standard deviations and categorical data as frequency and percentage. To evaluate the primary and secondary end points, independent samples Student's t test was used between the CR and non-CR arms and the CD and non-CD arms.

The dependent-sample Student's t-test was used to compare the means of HbA1c levels, BP, BW and LDL-C between baseline and those at 52 weeks and 104 weeks in each arm. The statistical analyses were performed using SPSS 24.0 (IBM Japan Inc., Tokyo, Japan). $p < 0.05$ was considered statistically significant.

RESULTS

Participant Characteristics

A total of 98 participants were analyzed: 49 (81.7%) in the CR arm, 49 (81.7%) in the non-CR arm, 52 (83.9%) in the CD arm, and 46 (79.3%) in the non-CD arm (Fig. 1). One participant in the CR arm, two in the non-CR arm, and three in the non-CD arm were dropped because of death, onset of cancer, and loss to follow-up.

The average age of the participants in the CR and non-CR arms was 68.7 ± 8.8 and 64.9 ± 10.2 years, respectively; the ratio of females was 40.8% and 40.8%; diabetes duration was 18.1 ± 8.7 and 17.0 ± 9.9 years; HbA1c levels were $7.9 \pm 0.8\%$ and $7.8 \pm 0.9\%$; SMBG frequency was 2.2 ± 1.1 and 1.9 ± 0.8 times/day. The average age of the participants in the CD and non-CD arms was 66.4 ± 9.5 and 67.3 ± 9.9 years, respectively; the ratio of females was 40.4% and 41.3%; diabetes duration was 18.7 ± 10.2 and 16.2 ± 8.1 years; HbA1c levels were $7.9 \pm 0.9\%$ and $7.8 \pm 0.9\%$; SMBG frequency was 2.1 ± 1.0 and 2.0 ± 0.9 times/day (Table 1).

HbA1c Findings

The HbA1c levels (mean ± SE) in the CR arm were significantly decreased from baseline by $-0.29 \pm 0.12\%$ (from $7.91 \pm 0.12\%$ to $7.62 \pm 0.15\%$, $p = 0.019$) at the end of the intervention period (24 weeks) and by $-0.31 \pm 0.11\%$ (from $7.91 \pm 0.12\%$ to

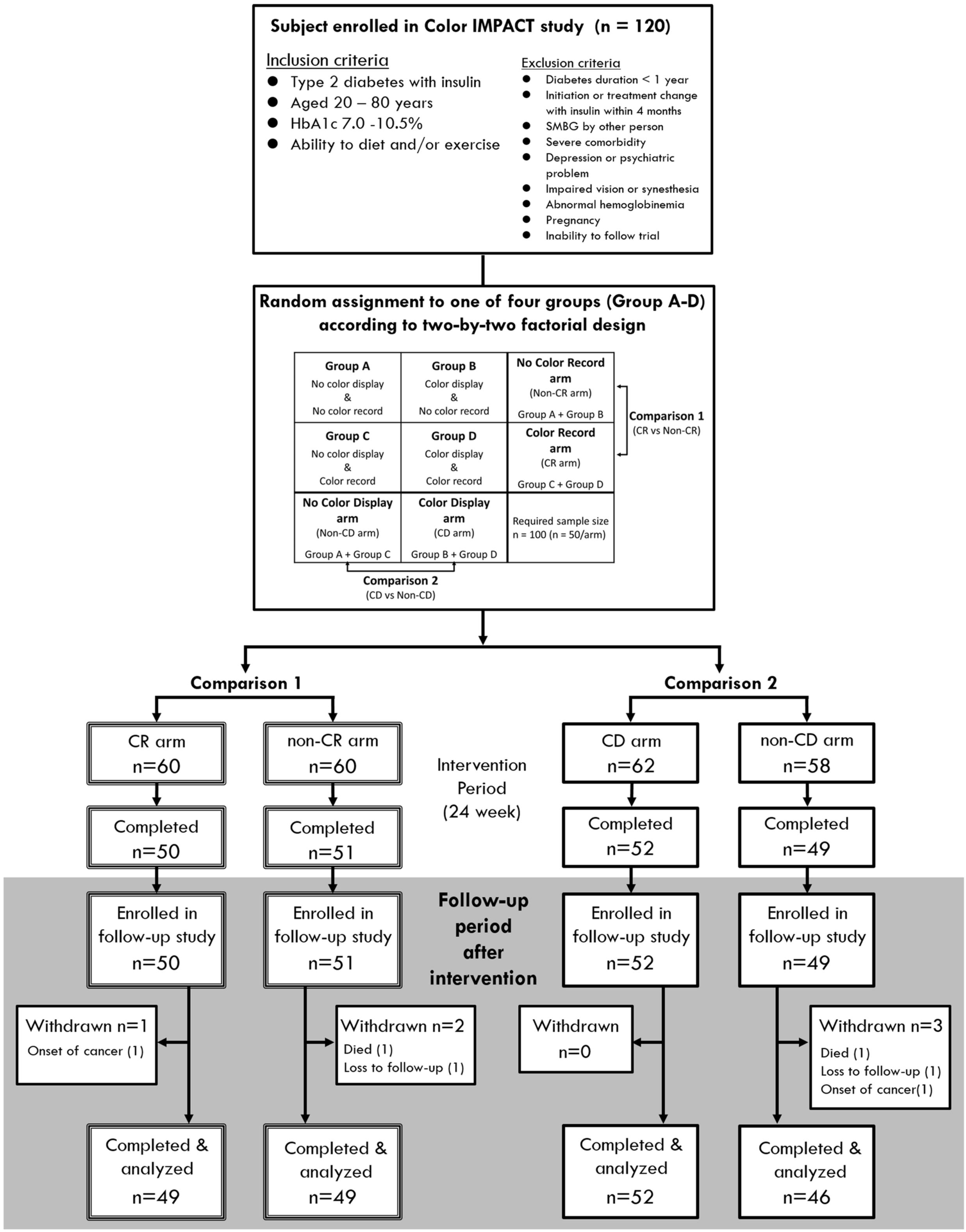


Fig. 1 Study design of the Color IMPACT study and flow chart of the participants

Table 1 Baseline demographics of study participants

Variables	Comparison 1		Comparison 2	
	CR arm n = 49	Non-CR arm n = 49	CD arm n = 52	Non-CD arm n = 46
Age (years)	68.7 ± 8.8	64.9 ± 10.2	66.4 ± 9.5	67.3 ± 9.9
Female (%)	40.8	40.8	40.4	41.3
Diabetes duration (years)	18.1 ± 8.7	17.0 ± 9.9	18.7 ± 10.2	16.2 ± 8.1
HbA1c (%)	7.91 ± 0.83	7.81 ± 0.90	7.93 ± 0.85	7.78 ± 0.87
SMBG frequency (times/day)	2.2 ± 1.1	1.9 ± 0.8	2.1 ± 1.0	2.0 ± 0.9
SBP (mmHg)	136.4 ± 18.9	128.0 ± 14.7	133.9 ± 19.7	130.9 ± 14.1
DBP (mmHg)	73.4 ± 10.5	71.2 ± 13.0	73.7 ± 10.9	70.5 ± 12.7
Body weight (kg)	63.1 ± 11.7	64.2 ± 15.0	63.5 ± 12.1	63.8 ± 14.9
BMI (kg/m^2)	24.7 ± 3.5	24.3 ± 4.0	24.1 ± 3.2	24.9 ± 4.3
LDL-C (mg/dl)	99.5 ± 24.8	101.1 ± 26.0	97.4 ± 24.7	103.4 ± 25.8

Data are mean ± SD

SMBG self-monitoring of blood glucose, *SBP* systolic blood pressure, *DBP* diastolic blood pressure, *BMI* body mass index, *LDL-C* low-density lipoprotein cholesterol

7.60 ± 0.14%, p = 0.010) at 52 weeks. However, HbA1c levels were back to the baseline levels at 104 weeks (− 0.05 ± 0.09%, from 7.91 ± 0.12% to 7.86 ± 0.14%) (Fig. 2a, b). The differences in change in HbA1c levels between the CR and non-CR arms were − 0.33% (95% CI, − 0.65 to − 0.02%; p = 0.037) at 24 weeks and − 0.40% (95% CI, − 0.73 to − 0.06%; p = 0.020) at 52 weeks with significant differences, respectively, and − 0.05% (95% CI, − 0.35 to 0.25) at 104 weeks without a significant difference (Fig. 2b).

On the other hand, HbA1c levels in the CD arm were not significantly changed at 24 weeks (− 0.12 ± 0.11%, from 7.78 ± 0.13% to 7.66 ± 0.16%), 52 weeks (− 0.20 ± 0.14%, from 7.93 ± 0.12% to 7.73 ± 0.18%), or 104 weeks (− 0.15 ± 0.10%, from 7.93 ± 0.12% to 7.78 ± 0.14%) (Fig. 2c, d). There were no significant differences in the change in HbA1c levels between the CD and non-CD arms at 24 weeks (−0.00%; 95% CI, −0.32 to 0.31), 52 weeks (− 0.19%; 95% CI, − 0.53 to 0.15) or 104 weeks (− 0.27%; 95% CI, − 0.57 to 0.02) (Fig. 2d).

BP, BW, and Lipid Profile

SBP (mean ± SE) in the CR arm changed from 136.4 ± 3.6 mmHg to 129.7 ± 3.1 mmHg (− 6.8 mmHg; 95% CI, − 15.0 to 1.4) at 24 weeks to 127.2 ± 2.6 mmHg (− 9.3 mmHg; 95% CI, − 18.0 to − 0.6; p = 0.038) at 52 weeks and to 132.0 ± 2.4 mmHg (− 4.4 mmHg; 95% CI, − 11.6 to 2.8) at 104 weeks. SBP was significantly decreased in the CR arm compared with that in the non-CR arm at 52 weeks (− 13.2 mmHg; 95% CI, − 24.1 to − 2.3; p = 0.019) (Fig. 3a). DBP changed from 73.4 ± 2.0 to 69.1 ± 2.1 mmHg (− 4.3 mmHg; 95% CI, − 9.3 to 0.8) at 24 weeks, to 70.6 ± 2.2 mmHg (− 2.8 mmHg, 95% CI, − 9.3 to 3.7) at 52 weeks, and to 68.6 ± 1.7 mmHg (− 4.7 mmHg; 95% CI, − 9.2 to − 0.3; p = 0.038) at 104 weeks in the CR arm. DBP was significantly decreased in the CR arm compared with that in the non-CR arm at 104 weeks (− 5.9 mmHg; 95% CI, − 11.7 to − 0.2; p = 0.044) (Fig. 3c).

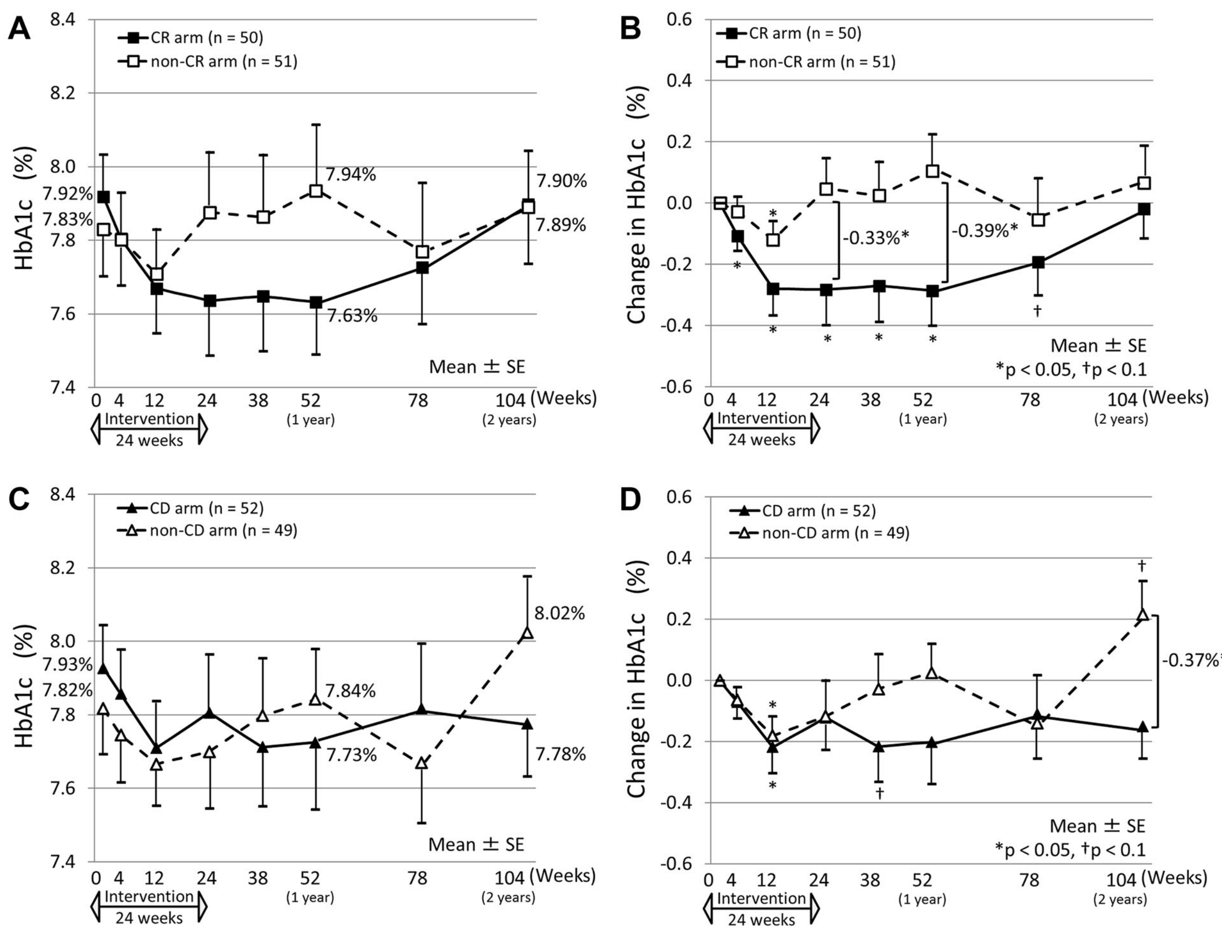


Fig. 2 HbA1c levels during the study. **a**, **c** HbA1c levels during a 104-week study period in **a** the color record (CR) and non-CR arms and **c** the color display (CD) and non-CD arms. **b**, **d** Change in HbA1c levels during a 104-week study period in **b** the CR and non-CR arms and **d** the CD and non-CD arms

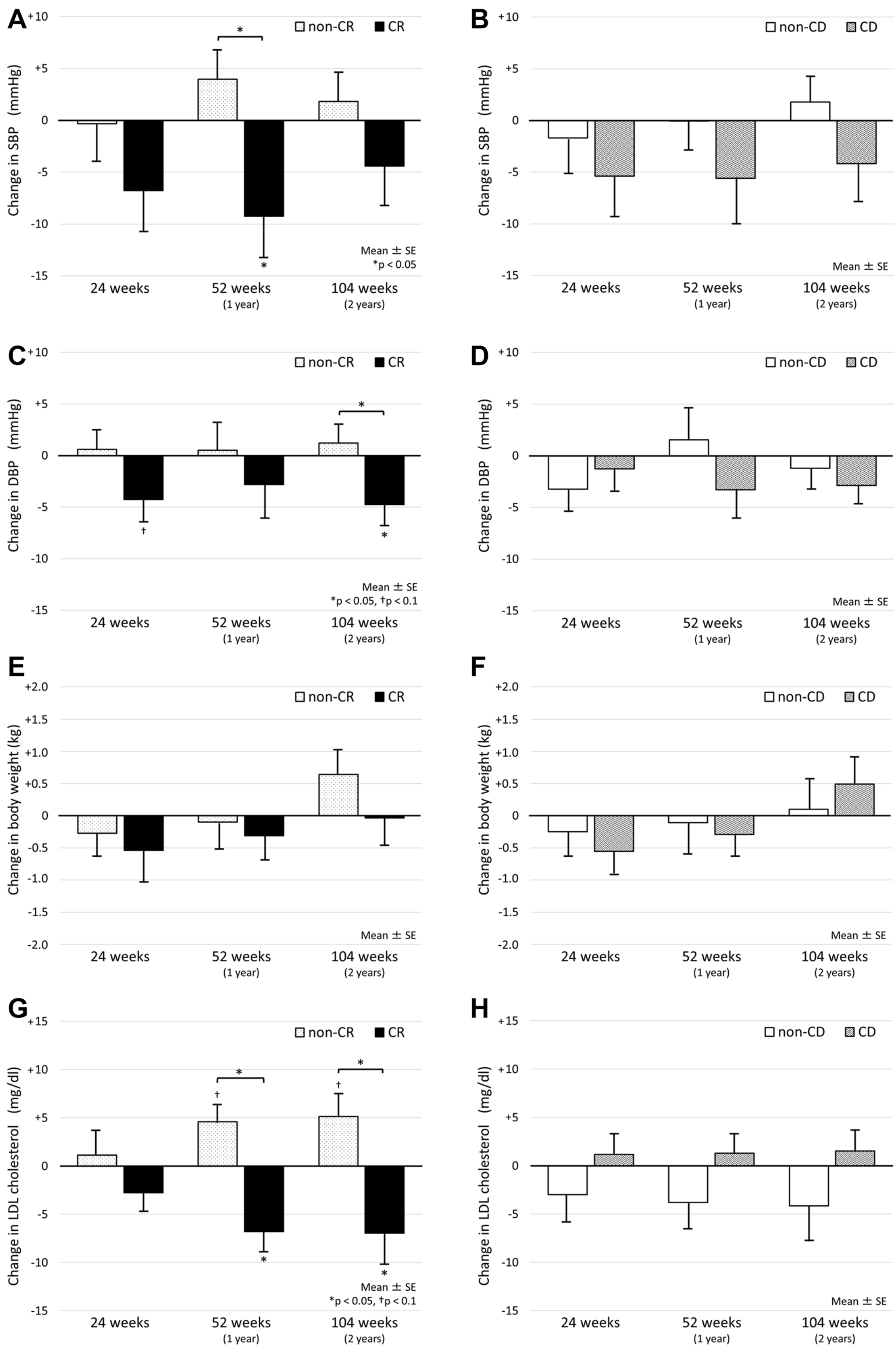
SBP and DBP were not significantly changed in the CD arm at 24, 52, and 104 weeks, and no significant difference was observed in change in SBP and DBP between the CD and non-CD arms at the indicated time points (Fig. 3b, d).

BWs were not significantly changed in all arms at any observed time points, and no significant difference was observed in change in BW between the CR and non-CR arms and the CD and non-CD arms (Fig. 3e, f).

LDL-C levels were changed from 99.5 ± 3.7 to 96.8 ± 3.5 mg/dl (– 2.7 mg/dl; 95% CI, – 7.0 to 1.6) at 24 weeks, to 92.8 ± 3.0 mg/dl (– 6.8 mg/dl; 95% CI, – 11.5 to – 2.1; $p = 0.006$) at 52 weeks, and to 92.5 ± 4.0 mg/dl (– 7.0 mg/dl; 95% CI, – 13.6 to – 0.5; $p = 0.036$) at 104 weeks. LDL-C was significantly decreased in the CR arm compared with that in the non-CR arm at 52 weeks (– 11.4 mg/dl; 95% CI, – 18.1 to – 4.6, $p = 0.001$) and at 104 weeks (– 12.1 mg/dl; 95% CI, – 20.5 to – 3.7; $p = 0.005$) (Fig. 3g).

LDL-C levels were not significantly changed in the CD arm at 24, 52, and 104 weeks, and

Fig. 3 Change in systemic blood pressure (SBP), diastolic blood pressure (DBP), body weight (BW), and low-density lipoprotein cholesterol (LDL-C) levels during the follow-up period. **a** Change in SBP, **c** DBP, **e** BW, and **g** LDL-C in the color record (CR) and non-CR arms. **b** Change in SBP, **d** DBP, **f** BW, and **h** LDL-C in the color display (CD) and non-CD arms ▶


A
B
C
D
E
F
G
H
non-CR
CR
non-CD
CD
Change in SBP (mmHg)
Change in DBP (mmHg)
Change in body weight (kg)
Change in LDL cholesterol (mg/dl)
24 weeks
52 weeks
(1 year)
104 weeks
(2 years)
Mean ± SE
*p < 0.05
*p < 0.05, †p < 0.1

there was no significant difference in change in LDL-C between the CD and non-CD arms at the indicated time points (Fig. 3h).

DISCUSSION

The aim of the present 2-year study was to evaluate the sustained effect of two color indication methods used in SMBG, CR and CD, on metabolic parameters in less frequently insulin-treated type 2 diabetes. The study demonstrates significant and clinically relevant metabolic improvements such as HbA1c levels (− 0.40%), SBP (− 13.2 mmHg), and LDL-C levels (− 11.4 mg/dl) only in the CR arm after 1 year. In the next 1-year period, HbA1c levels and SBP returned to the baseline levels, but reduction of LDL-C levels continued. On the other hand, there were no significant improvements in HbA1c, BP, or LDL-C levels throughout the entire post-intervention period in the CD arm. These results indicate that metabolic improvement is prolonged after the completion of an intervention when a self-motivated method in diabetes self-management is used.

CR requires action by participants. They have to understand the measured value as a normal glycemic level, hyperglycemia, or hypoglycemia and record this in black, red, or blue pencil, respectively, in their notes. On the other hand, CD is a passive method of SMBG usage. The SMBG meter automatically shows participants that the measured value is high or low in the color display, but requires no immediate action. The majority of people with diabetes rely on SMBG to evaluate their self-management efforts [21]. However, many such people, especially those with less frequent SMBG, continue SMBG without any aim and take no action when their SMBG meter displays hyper- or hypoglycemia [22]. Thus, active engagement would seem to be essential for learning and understanding the information [23]. CR might therefore be an especially useful approach for people with diabetes to understand glycemic variability and positively change their behavior for better diabetes management.

Another point to notice is that both the physician and the participants were able to share a common goal for glycemic control in the CR arm [20]. This relationship of trust with healthcare professionals may have important effects on the motivation of people with diabetes [24]. A previous systematic review also found that a behavioral program with clinically important effects for type 2 diabetes were better delivered in person rather than by some form of technology (for example, a touch screen, website, or DVD) [25]. In this context, CR in SMBG may be beneficial in promoting mutual understanding and partnership between people with diabetes and healthcare professionals. In contrast, it was difficult for them to share their thoughts about SMBG data with healthcare professionals in CD arm in a timely manner.

In the present study, HbA1c, BP, and LDL-C levels were improved during the intervention period and at least for a 6-month post-intervention period only in the CR arm. By recording their blood glucose levels using color, it is easy for the participants to understand the effect of diet and exercise on glycemic control and to remember it for a long time. Therefore, they could continue diet and exercise therapy after the intervention was finished, while BW was not reduced in the CR arm. The BMI of participants was less than 25 kg/m^2 in all groups, so healthcare professionals did not make an effort to guide them to control BW. Nevertheless, BW was not increased during the 2-year post-intervention period in the CR arm.

CR is thus an efficient and economical strategy for providing diabetes care to numerous people with diabetes with a limited number of diabetes educators having limited time and budget. People with diabetes receive intensive diabetes education and care for a certain defined period and then continue with personal, self-motivated action. If glycemic control and other metabolic risk factors worsen, healthcare professionals can then re-educate them with adequate patient-centered approaches.

Our study has several limitations that need to be considered. First, self-management performance and psychologic aspects were not evaluated in the follow-up study. Hence, participants' contributing factors related to changes in HbA1c levels, BP, and lipid profile were undetermined. Second, participants were recruited from a single center. Such evidence does not always reflect overall features of people with type 2 diabetes.

CONCLUSION

The CR method in SMBG shows a sustained beneficial effect on diabetes care. An improvement in HbA1c, BP, and LDL-C levels was maintained without any intensive care at least for 6 months after the intervention was finished. CR is thus a simple, economical, and patient-oriented SMBG method that motivates self-action to diabetes self-management. Healthcare professionals should provide such self-motivating approaches to people with diabetes according to individual diabetic conditions and lifestyles.

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Compliance with Ethics Guidelines. All procedures performed in the follow-up study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent for this follow-up study was exempted by the IRB because written informed consent was obtained from all individual participants in the Color IMPACT study. The protocol for the follow-up study was approved by the IRB of Kyoto University Hospital (R0886).

Data Availability. The data sets during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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