

**THE MONITOR TRIAL**

**Effect of Glucose Monitoring on Patient and Provider Outcomes in Non-insulin Treated Diabetes**

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**“To Test or Not to Test?”**  
 ... evaluating the impact of glucose monitoring on the control of Type-2 Diabetes

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**Disclosure to Participants**

- Notice of Requirements For Successful Completion
  - Please refer to learning goals and objectives
  - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours
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  - UNC received financial support from the following companies for research (Dr. Young is PI/co PI on the studies)
  - Eli Lilly, BMS, GI Dynamics, PhaseBio, Medtronic, Sanofi, Tolerex, Halozyme, J&J, Andromeda, GSK, BI, Intarcia, Lexicon, Orexigen, Scion Neurostim, Takeda, Theracos, Novo Nordisk
  - Dr. Young serves on Medical Advisory Board/Steering Committees for: POPs Diabetes, DEXCOM
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**Outline**

- PCORI
  - Engagement of Stakeholders in Study Design
- Study Design
- Study Results
- Conclusions

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**What is PCORI?**

**Patient Centered Outcomes Research Institute** 

**Mission:**  
 PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research *guided by patients, caregivers and the broader health care community.*

**Vision:**  
 Patients and the public have the information they need to make decisions that reflect their desired health outcomes.

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**What is PCORI?**

- PCORI was created by the Affordable Care Act of 2010 as an independent, non-profit, non-governmental organization.
- Funding is provided by the general fund of the US Treasury and by an annual \$2 fee per individual assessed on Medicare, private health insurance and self-insured plans.
- PCORI is interested in funding research that is directly relevant to patients

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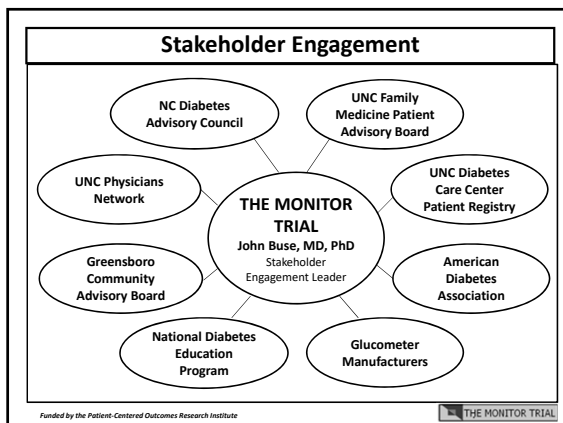
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### Input given during study design

Stakeholders	Input Provided	How it shaped our design
North Carolina Diabetes Advisory Council	-consider health literacy -policy subgroup would be useful to engage for this work	-Engaged the Center for Diabetes Translation and Research literacy to assist with message tailoring -Tailoring algorithm that could be used in office
UNC Family Medicine Patient Advisory Board	-emphasize quality of life questions (can I feel better or improve my ADLs?)	-Added quality of life to the outcomes
Greensboro Community Advisory Board	-important outcomes: quality of life, hypoglycemia, health care service use, patient empowerment -CMEs for providers important -query patient/provider community care	-Hypoglycemia added as an outcome -explore CME for providers -add survey questions on patient-provider communications
Diabetes Center Patient Registry	A1C is important in addition to Quality of life Patients willing to be randomized to no SMBG or daily SMBG	-A1C designated primary outcome -Overall recruitment feasibility confirmed
UNCPN Medical Directors	Testing is quite variable in real world settings	-Designed three arm plan to address this reality and better respond to pragmatic patient issues

- ### Stakeholder Engagement
- Meetings (Stakeholders and Team)
    - Year 1
      - Kickoff (Stakeholders and Team ) on August 28<sup>th</sup> Today!
      - ~8 calls, 1 hour with Team
    - Year 2
      - ~4 calls, 1 hour with Team
    - Year 3
      - Review of Results
      - ~8 calls, 1 hour with Team
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### “To Test or Not To Test”

For SMBG to be an effective self-management tool in NIT DM, the patient and the health care provider must both actively engage in performing, interpreting, and acting upon the SMBG values.

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### Project Overview

Assess the impact of 3 SMBG testing approaches over one year on patient-centered outcomes in 450 patients with non-insulin treated T2DM with the real-world, clinic setting

**Group 1:** No SMBG Testing

**Group 2:** Once daily SMBG Testing with standard patient feedback  
(Glucose values reported on monitor)

**Group 3:** Once daily SMBG Testing with enhanced patient feedback  
(Standard plus automated tailored feedback messaging following each SMBG testing event delivered to the patient through the monitor)

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### AIM 1

Assess SMBG effectiveness on two primary patient-centered outcomes, glycemic control and quality of life, over 52 weeks in 450 non-insulin treated patients with T2DM

- a) Compare 3 different SMBG testing approaches
- b) Assess glycemic and quality of life across the following subgroups: prior experience using SMBG, duration of T2DM, baseline degree of glycemic control, anti-hyperglycemic treatment, age, race/ethnicity and health literacy

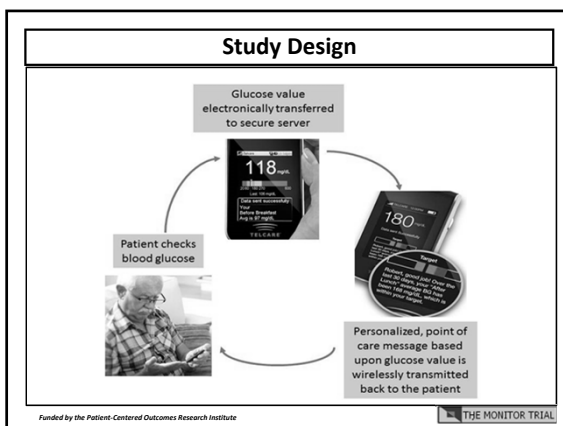
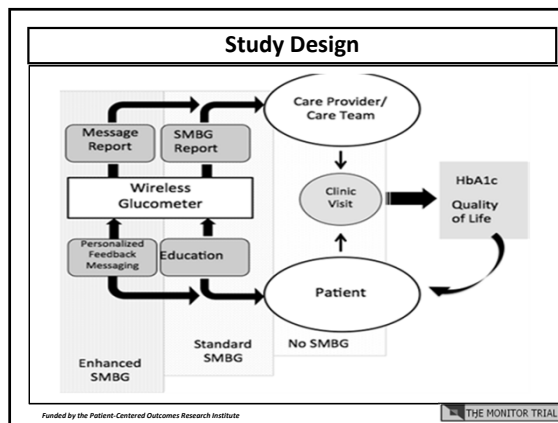
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### AIM 2

Evaluate the SMBG impact on several secondary patient-centered outcomes over 52 weeks including

- Diabetes treatment satisfaction, diabetes symptoms, diabetes self-efficacy, diabetes related distress, and diabetes self-care activities
- Patient-provider communication

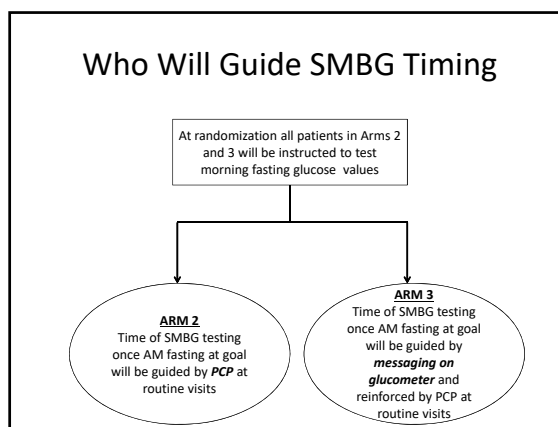
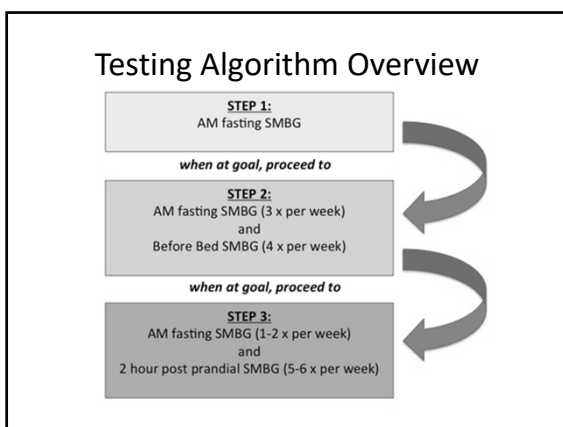
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### Sample Messages


<p><b>Sample Messages for Blood Glucose Values at Goal</b></p> <ul style="list-style-type: none"> <li>• "You are right on target. Remember to check your blood sugar tomorrow morning."</li> <li>• "Keep up the good work."</li> <li>• "Outstanding!"</li> <li>• "Way to go. Keep checking every morning before breakfast!"</li> <li>• "Your blood glucose goal is between 70-130 in the morning before you eat. You are doing marvelously."</li> </ul>
<p><b>Sample Messages for Blood Glucose Values that are Mildly Elevated</b></p> <ul style="list-style-type: none"> <li>• "Keeping track of the foods you are eating and the physical activity you are doing may help you pinpoint reasons why your blood sugars are running high."</li> <li>• "This number is a bit off target. Remember to check again tomorrow morning before eating."</li> <li>• "Your target in the morning before eating is 70-130."</li> <li>• "Staying on track with your diabetes can be tough at times. You can do this! Aim for a target fasting blood glucose value in the morning between 70-130."</li> </ul>
<p><b>Sample Messages for Blood Glucose Values that are Very Elevated</b></p> <ul style="list-style-type: none"> <li>• "Please discuss with your health care provider to talk about ways to get your blood sugars down to a more healthy range."</li> <li>• "Please consider making an appointment with your doctor. Your blood sugars have been too high lately. Your target before breakfast is 70-130."</li> <li>• "Time to check in with your primary care provider about these blood sugar numbers. They have been running too high."</li> </ul>

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**TREATMENT RECOMMENDATION B  
IDEAL FASTING GLUCOSE**

Your patient is doing a great job!



Congratulate them on meeting their target fasting glucose values.

Encourage them to continue engaging in healthy behaviors.

Discuss any questions patient may have regarding their diabetes.

**Time for a change!**  
Instruct your patient to check awakening fasting glucose values 3-4 days per week and ADD before bed glucose monitoring on the other 3-4 nights. Your patient will still only be checking glucose one time per day.

**TREATMENT RECOMMENDATION C  
ELEVATED FASTING GLUCOSE**

Consider increasing or adding additional medication that target fasting hyperglycemia including:

- Metformin
- Phosphodiesterase
- GLP-1 Agonists
- Long Acting Sulfonylureas (glimepiride)
- DPP-4 inhibitors
- SGLT2 inhibitors
- Basal Insulin

TOPICS FOR DISCUSSION WITH YOUR PATIENT	TREATMENT RECOMMENDATIONS
<b>MEDICATION USE</b> <ul style="list-style-type: none"> <li>How often are medications skipped/missed?</li> <li>Why are medications missed/missed?</li> <li>What barriers is the patient facing?</li> <li>Are there medication side effects?</li> </ul>	<ul style="list-style-type: none"> <li>Simplification to once daily regimen</li> <li>Use generics/lowest tier medications</li> <li>Change agents if side effects occur</li> <li>Encourage use of pill box</li> </ul>
<b>MEAL/SNACKING PATTERNS</b> <ul style="list-style-type: none"> <li>What are they eating routinely?</li> <li>Are they eating out of home?</li> <li>What types of beverages?</li> <li>Is snacking occurring?</li> </ul>	<ul style="list-style-type: none"> <li>Eat fewer meals out of the home</li> <li>Avoid sugar sweetened beverages</li> <li>Discuss the impact of carbohydrates on blood glucose values</li> <li>Avoidance of snacking if possible</li> <li>Offer referral to CDC or nutritionist</li> </ul>
<b>PHYSICAL ACTIVITY</b> <ul style="list-style-type: none"> <li>How much daily physical activity?</li> <li>Are they meeting recommended goals?</li> <li>Do they understand the impact of physical activity on glucose?</li> </ul>	<ul style="list-style-type: none"> <li>Review current recommendations, 30 minutes most days of the week</li> <li>Build physical activity into daily routine</li> <li>Discuss how physical activity affects glucose values</li> </ul>
<b>WEIGHT LOSS</b> <ul style="list-style-type: none"> <li>Begin with non-threatening words like "healthier weight", "excess weight"</li> <li>What is the overall weight trend?</li> <li>What has/hasn't worked in the past?</li> <li>If indicated, has bariatric surgery been discussed?</li> </ul>	<ul style="list-style-type: none"> <li>Discuss what a healthy weight would be</li> <li>Encourage setting attainable goals</li> <li>Encourage keeping daily food diaries</li> <li>Use online and mobile apps like myfitnesspal.com or livestrong.com</li> <li>Referral to nutritionist</li> <li>Offer referral to bariatric surgery</li> </ul>

**Provide encouragement to your patient to continue daily SMBG monitoring each morning before they eat breakfast.**

**Study Population**

- 15 Primary Care Practices in Central NC Practices
- Patients
  - T2DM diagnosed after age 30 not on insulin
  - Established patient at a participating UNCPN practice who identifies a UNCPN health care provider as their primary provider of diabetes care
  - A1C 6.5%-9.5%
  - English speaking
  - Non pregnant
  - Not seeing or planning to see Endocrine

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**Outcomes**

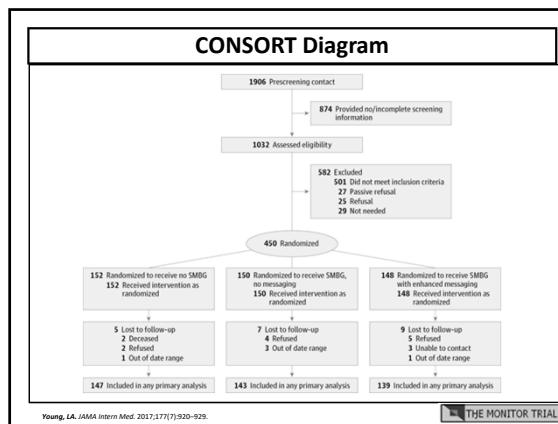
- Primary Outcomes
  - Change in A1c from baseline to 52 weeks
  - Quality of life (measured by SF-36)
- Secondary Outcomes
  - Diabetes Related Quality of Life (PAID, DM Symptom CL)
  - Diabetes Self-Care (SDSCA)
  - Diabetes Treatment Satisfaction
  - Patient-Provider Communication (CAT)

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**Outcomes**

- Potential Moderating Variables
  - Prior experience using SMBG
  - Age, race, ethnicity
  - Other co-morbidities
  - DM-related complications
  - Duration of DM
  - Prior experience with SMBG
  - Health literacy (Newest Vital Sign)

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### Baseline Characteristics

Characteristic	Randomization Group			Total (n = 450)
	No SMBG (n = 152)	SMBG, No Messaging (n = 150)	SMBG With Messaging (n = 148)	
Age, median (range), y	61 (31-89)	63 (32-82)	61 (35-92)	61 (31-92)
Sex, No. (%)				
Male	74 (48.7)	67 (44.7)	66 (44.6)	207 (46.0)
Female	78 (51.3)	83 (55.3)	82 (55.4)	243 (54.0)
Race, No. (%)				
Black	42 (27.6)	55 (36.7)	51 (34.5)	148 (32.9)
White	104 (68.4)	89 (59.3)	86 (58.1)	279 (62.0)
Other	6 (3.9)	6 (4.0)	11 (7.4)	23 (5.1)
Ethnicity, non-Latino Hispanic, No. (%)	148 (97.4)	147 (98.7)	146 (98.6)	441 (98.2)
Education, No. (%)				
<High school	6 (4.0)	10 (6.7)	9 (6.1)	25 (5.6)
High school/some college	95 (62.5)	87 (58.0)	89 (60.1)	271 (60.4)
College or higher	50 (33.1)	53 (35.3)	50 (33.8)	153 (34.1)
BMI, median (range)	33 (22-58)	33 (21-62)	34 (21-75)	33 (21-75)
Low health literacy, No. (%) <sup>a</sup>	62 (40.8)	54 (36.5)	55 (37.2)	171 (38.2)
Years with diabetes, median (range)	6 (0-45)	6 (0-44)	6 (0-50)	6 (0-50)
Diabetes 1 y or less, No. (%)	25 (16.4)	27 (18.0)	14 (9.5)	66 (14.7)
No. of comorbidities, median (range)	3 (0-9)	3 (0-10)	3 (0-8)	3 (0-10)

Young, LA. JAMA Intern Med. 2017;177(7):920-929.

### Baseline Characteristics

Characteristic	Randomization Group			Total (n = 450)
	No SMBG (n = 152)	SMBG, No Messaging (n = 150)	SMBG With Messaging (n = 148)	
Use of SMBG, No. (%)				
Current	114 (75.0)	108 (72.0)	116 (78.4)	338 (75.1)
Ever	138 (90.8)	135 (90.0)	143 (96.6)	416 (92.4)
Testing preference, No. (%)				
Any SMBG	63 (41.4)	56 (37.3)	59 (39.9)	178 (39.6)
No SMBG	31 (20.4)	34 (22.7)	32 (21.6)	97 (21.6)
Uncertain	2 (1.3)	1 (0.7)	1 (0.7)	4 (0.9)
No preference	56 (36.8)	59 (39.3)	56 (37.8)	171 (38.0)
Diabetes medications, No. (%) <sup>b</sup>				
Metformin	123 (80.9)	115 (76.7)	120 (81.1)	358 (79.6)
Sulfonylurea or glinide	51 (33.6)	50 (33.3)	60 (40.5)	161 (35.8)
Thiazolidinedione	8 (5.3)	3 (2.0)	10 (6.8)	21 (4.7)
GLP-1 agonist	5 (3.3)	2 (1.3)	10 (6.8)	17 (3.8)
DPP-4 inhibitor	12 (7.9)	11 (7.3)	17 (11.5)	40 (8.9)

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### Primary Outcomes by Randomization Group

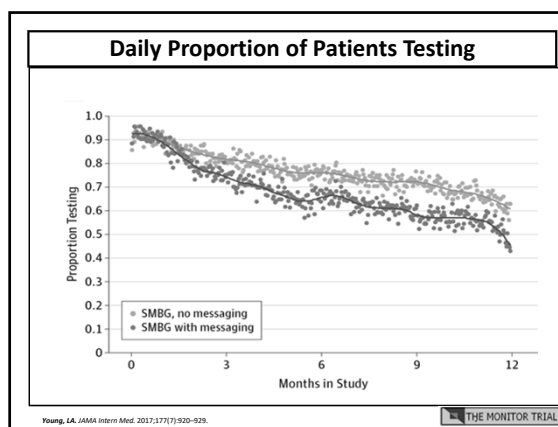
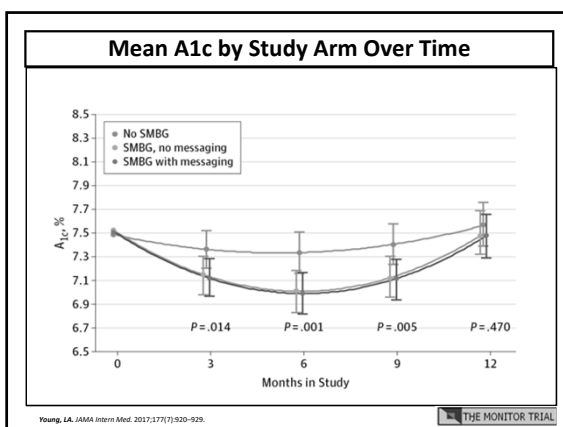
Variable	Randomization Group			P Value Overall <sup>a</sup>	Contrast <sup>b</sup>
	No SMBG (n = 152)	SMBG, No Messaging (n = 150)	SMBG With Messaging (n = 148)		
<b>Hemoglobin A<sub>1c</sub>, %<sup>c</sup></b>					
Baseline	152	150	148	7.51 (1.12)	
Follow-up	147	141	139	7.55 (1.10)	74
Change	147	141	139	-0.05 (1.00)	48
<b>Health-Related Quality of Life, SF-36<sup>d</sup></b>					
Physical score					
Baseline	152	150	148	46.22 (10.13)	
Follow-up	143	142	135	46.44 (9.88)	48
Change	143	142	135	-0.35 (8.95)	50
Mental score					
Baseline	152	150	148	53.43 (9.58)	
Follow-up	143	142	135	52.57 (10.39)	50
Change	143	142	135	-1.39 (8.85)	>99

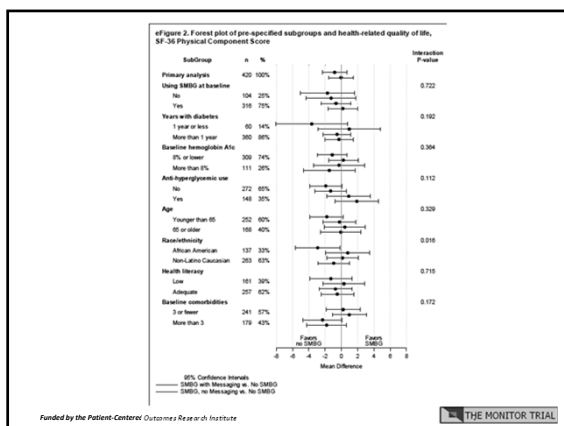
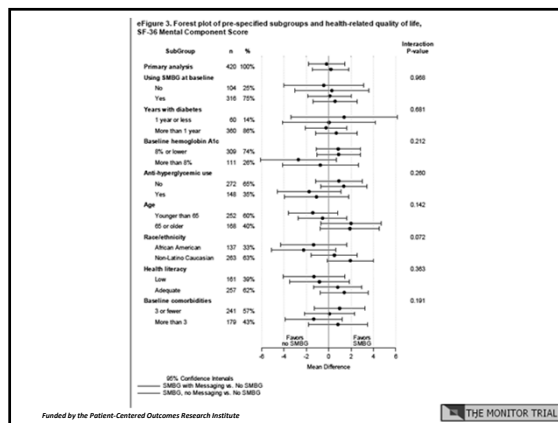
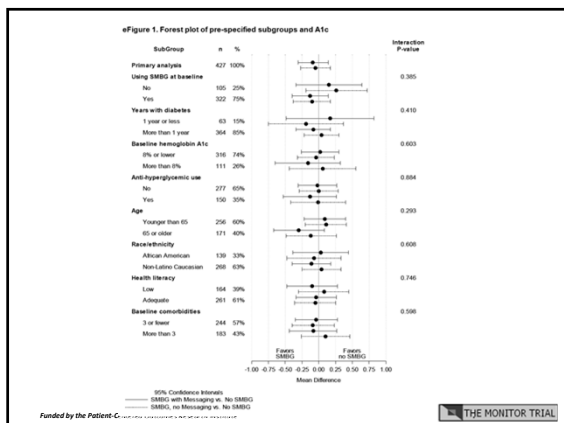
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### Secondary Outcomes by Randomization Group

Variable	Randomization Group			P Value Overall <sup>a</sup>	Contrast <sup>b</sup>
	No SMBG (n = 152)	SMBG, No Messaging (n = 150)	SMBG With Messaging (n = 148)		
<b>Diabetes complications<sup>c</sup></b>					
Baseline	152	150	148	13.07 (28.18)	
Follow-up	143	142	135	9.04 (24.54)	21
Change	143	142	135	-3.94 (24.76)	0.06
<b>Diabetes self-management score (SDS)<sup>d</sup></b>					
Baseline	152	150	148	20.73 (22.63)	
Follow-up	143	142	135	19.80 (21.42)	0.06
Change	143	142	135	-0.33 (14.76)	0.98
<b>Diabetes Treatment Satisfaction<sup>e</sup></b>					
Baseline	152	150	148	4.27 (6.58)	
Follow-up	143	142	135	4.46 (6.49)	28
Change	143	142	135	0.20 (6.49)	0.98
<b>Diabetes Medication Adherence<sup>f</sup></b>					
Baseline	152	150	148	3.46 (1.34)	
Follow-up	143	142	135	3.87 (1.32)	<0.001
Change	143	142	135	0.41 (0.93)	<0.001
<b>Diabetes Medication Adherence (Self-Reported)<sup>g</sup></b>					
Baseline	152	150	148	2.64 (2.93)	
Follow-up	143	142	135	3.39 (2.30)	<0.001
Change	143	142	135	0.75 (2.30)	<0.001
<b>Diabetes Treatment Satisfaction<sup>h</sup></b>					
Baseline	149	147	148	11.89 (4.96)	
Follow-up	135	131	135	11.74 (5.90)	48
Change	135	131	135	-0.20 (5.99)	0.98
<b>Diabetes Medication Adherence (Self-Reported)<sup>i</sup></b>					
Baseline	152	150	148	4.49 (5.70)	
Follow-up	143	142	135	4.33 (5.71)	48
Change	143	142	135	-0.16 (5.71)	0.98

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**Limitations**

- Primary care
- Did not explicitly engage other support staff (CDEs, nutritionists)
- Unable to enforce health care providers compliance with recommendations

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**Conclusions**

- In patients with non-insulin-treated type 2 diabetes, we observed no clinically or statistically significant differences at 1 year in glycemic control or HRQOL between patients who performed SMBG compared with those who did not perform SMBG.
- The addition of this type of tailored feedback provided through messaging via a meter did not provide any advantage in glycemic control.

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