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2 **Supplement**  
3

4 **Automated Text Message Navigation to Improve Outpatient Colonoscopy Show**  
5 **Rate and Bowel Preparation**  
6

7 This supplement provides additional information about the work. It contains the following items:  
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25 **Initial Protocol**

26 **Automated Text Message Navigation to Improve Outpatient Colonoscopy Show Rate and Bowel**  
27 **Preparation**

28

29 **Brief Description**

30 Outpatient colonoscopy adherence is negatively impacted by poor communication and challenges with  
31 bowel preparation. We plan to perform a randomized controlled trial at the Pennsylvania Presbyterian  
32 Medical Center to (1) provide text message-based educational and reminder messages to patients  
33 regarding a scheduled colonoscopy, and (2) evaluate the impact of the texting intervention on  
34 colonoscopy show rate and bowel preparation.

35

36 **Protocol**

37 **Abstract**

38 Colonoscopy is an effective screening technique for colorectal cancer (CRC) prevention, but many  
39 patients either do not show up or have poor bowel preparation for the procedure. We plan to evaluate  
40 the impact and feasibility of a text message-based program to provide patients with timely educational  
41 and reminder messages regarding their upcoming colonoscopy and bowel preparation process. In this  
42 pragmatic randomized controlled trial, we aim to (1) to provide text message-based educational and  
43 reminder messages to patients or support partners regarding a scheduled colonoscopy, and (2) to  
44 evaluate the impact of the texting intervention on colonoscopy show rate and bowel preparation. We  
45 will include patients who are scheduled for outpatient colonoscopy at the Pennsylvania Presbyterian  
46 Medical Center. After enrollment, patients will be randomized 1:1 to usual care (arm 1) or the text  
47 message-based intervention (arm 2, one week in duration). We will measure colonoscopy show rate  
48 with good/excellent bowel preparation as the primary outcome.

49

50 **Objectives**

51 **Overall objectives**

52 The specific aims of the study are to (1) to provide text message-based educational and reminder  
53 messages to patients or support partners regarding a scheduled colonoscopy, and (2) to evaluate the  
54 impact of the texting intervention on colonoscopy show rate and bowel preparation.

55

56 **Primary outcome variable(s)**

57 The primary outcome of the study will be colonoscopy show rate with good/excellent bowel preparation  
58 (binary).

59

60

61 **Secondary outcome variable(s)**

62 Secondary outcomes of the study will include colonoscopy show rate, bowel preparation quality (poor,  
63 fair, good, excellent), colonoscopy cancellation rate, timing of advance cancellation notification (days),  
64 and colonoscopy appointment no-show rate.

65

66 **Background**

67 Colorectal cancer (CRC) is the second leading cause of cancer death in the US, yet there are effective  
68 screening and treatment strategies that allow for early detection and treatment. CRC screening is  
69 recommended for all individuals aged 50-75, which could include stool testing or colonoscopy, but  
70 national rates are still suboptimal at 59-65%. Colonoscopy is an essential component of CRC screening,  
71 as it is also required if stool testing is positive. However, colonoscopy requires a complex process to  
72 identify an escort, purchase the preparation, take a day off from work, adhere to a clear liquid diet, and  
73 complete the split-dose preparation as recommended. This results in a significant no-show and  
74 cancellation rate, along with suboptimal preparation quality, which can lead to non-adherence and  
75 incomplete screening.

76

77 Current approaches to engaging patients include having nurses call patients before the procedure or  
78 patient navigators. However, it is often difficult to get patients on the phone, and these interventions  
79 can be costly, making it less scalable for clinical practices. Other interventions such as videos or mobile  
80 apps have been limited by poor user experience or limited engagement with the patient. There is an  
81 opportunity to leverage an automated text message navigation intervention using the Way to Health  
82 (WTH) platform to improve patient engagement prior to colonoscopy completion. The WTH platform is a  
83 Penn Medicine platform that is hosted on site at the University of Pennsylvania. The platform allows  
84 custom text messages to automatically be sent to patients, in addition to bidirectional message  
85 capabilities. WTH is protected by a secure firewall and is a HIPAA compliant platform.

86

87 In the past year, our team conducted a quality improvement pilot initiative using WTH that tested the  
88 feasibility and impact of a one-week text messaging protocol for patients who were scheduled for  
89 outpatient colonoscopy. The text messages sent to patients contained information about the  
90 preparation process and instructions, expectations about the procedure, and reminders about location  
91 and timing. Among the 21 patients enrolled in the pilot, we found high user acceptability and higher  
92 colonoscopy show rates as compared to baseline values at PPMC (90% versus ~50%). As such we believe  
93 that the texting intervention is feasible for testing in the context of a randomized controlled trial.

94

95 **Study Design**

96 Design

97 We will perform a pragmatic randomized controlled trial evaluating the impact of the text message-  
98 based intervention (arm 2) as compared to usual care alone (arm 1). Patient enrollment will be  
99 performed with assistance from the call center at the Pennsylvania Presbyterian Medical Center (PPMC),  
100 and/or through phone calls from a clinical research coordinator. After enrollment, patients will be  
101 randomized 1:1 to the arms listed above through the Way to Health platform. Although patients in arm  
102 2 may be enrolled weeks or months in advance of their colonoscopy, they will only receive intervention  
103 text messages in the 7 days prior to the scheduled colonoscopy. Usual care consists of a phone call from  
104 the PPMC endoscopy staff in the week prior to colonoscopy, if the patient is able to be reached. Patients  
105 are also given the endoscopy phone number, and may call to speak to staff if they have specific  
106 questions about their colonoscopy or need to reschedule. A detailed outline of study design can be  
107 found in the procedures sections.

108

### 109 **Study duration**

110 The duration of participation for patients in the intervention will be from the time of enrollment to the  
111 date of scheduled colonoscopy. However, the patient will only receive intervention text messages in the  
112 week prior to the scheduled colonoscopy. We will plan to recruit patients from November 2018 through  
113 January 2019. We estimate that the study will be completed by March 2019.

114

### 115 **Resources necessary for human research protection**

116 Describe research staff and justify that the staff are adequate in number and qualifications to conduct  
117 the research. Describe how you will ensure that all staff assisting with the research are adequately  
118 informed about the protocol and their research related duties. Please allow adequate time for the  
119 researchers to conduct and complete the research. Please confirm that there are adequate facilities for  
120 the research.

121

122 The project will take place at the Pennsylvania Presbyterian Medical Center (PPMC) at the University of  
123 Pennsylvania (UPENN). The team includes investigators experienced in clinical medicine, health behavior  
124 interventions, clinical trials, behavioral economics, and program evaluation. This study will be led by Dr.  
125 Shivan Mehta, MD, MBA, MSHP, Assistant Professor of Medicine and Associate Chief Innovation Officer  
126 for Penn Medicine. This study will be supported on a secure web portal on the Way to Health platform,  
127 modified to the specifications of this study. Additional study staff include a gastroenterology fellow,  
128 medical student, key PPMC endoscopy staff, and quality improvement specialists. Regular group  
129 meetings will be held at pivotal points in the trial in order to ensure compliance with protocol and  
130 research-related duties.

131

### 132 **Characteristics of the Study Population**

133 Target population

134 Eligibility Criteria: Patients will be eligible for study inclusion if they are age 18-85 years and are  
135 scheduled for outpatient colonoscopy to be completed at the PPMC outpatient endoscopy center. We  
136 will exclude patients if there are fewer than 10 days from time of scheduling to the scheduled date of  
137 colonoscopy. The target enrollment sample size is 400 patients—200 in arm 1 (usual care) and 200 in  
138 arm 2 (usual care plus texting intervention). This number is based on sample size calculations using data  
139 from a previous pilot, which suggests that a total sample size of 200 patients will have greater than 80%  
140 power to detect a 15% difference in the primary outcome.

141

142 Subjects enrolled by Penn Researchers

143 400

144

145 Subjects enrolled by Collaborating Researchers

146 0

147

#### 148 **Accrual**

149 Participants in the study will be planned for outpatient colonoscopy at the Pennsylvania Presbyterian  
150 Medical Center (PPMC). Once a patient is confirmed to meet eligibility criteria, patient enrollment will  
151 be performed with assistance from the call center at PPMC, and/or through phone calls from a clinical  
152 research coordinator. When patients have a physician order for a colonoscopy, the patient must contact  
153 the call center in order to schedule the colonoscopy. The call center staff have agreed to discuss the  
154 research project and enroll patients using a script to be approved by the IRB. Importantly, we are  
155 requesting a waiver of consent for several reasons: (1) the study presents no more than minimal risk of  
156 harm to participants, (2) the patients who are randomized to either arm will not be deprived of any  
157 standard care available in the status quo and thus the study will not violate their rights or welfare, (3)  
158 the study could not be practicably completed without such a waiver, as the scheduling process is  
159 handled over the phone by call center staff, and (4) requiring standard informed consent would require  
160 an additional touchpoint by the research coordinator and the consent process would preclude us from  
161 evaluating the intended intervention by introducing selection bias and altering the intervention that  
162 patients receive. After enrollment, patients will be 1:1 randomized to arm 1 or arm 2 using the Way to  
163 Health platform.

164

165 Key inclusion criteria

166 Eligibility Criteria: Patients between ages 18 and 85 years who are scheduled for outpatient colonoscopy  
167 at PPMC and have a cell phone

168

169 Key exclusion criteria

170 Exclusion Criteria: Patients will be excluded if there are fewer than 10 days between the time of  
171 enrollment and time of scheduled colonoscopy. This will ensure that patients randomized to arm 2 will  
172 have sufficient time to receive the full text message intervention. Patients will also be excluded if they  
173 do not meet all of the inclusion criteria, or if they refuse participation in text messaging.

174

175

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177

178

## 179 **Procedures**

180 Screening – Phase 1: Patients who have a physician order for a colonoscopy will call the PPMC call center  
181 in order to schedule their procedure. At this time, the call center staff will screen the patient for  
182 eligibility (age criteria and text messaging ability) and will explain the details of the study following a pre-  
183 determined script. Patients who agree to participate in the study will have their cell phone number  
184 recorded. A list of these patients will be forward to the clinical research coordinator on a weekly basis,  
185 who will confirm patient eligibility and then manually enter patients into the WTH platform. Based on  
186 our experience with the QI pilot described above, we estimate needing to screen between 500 and 600  
187 patients to meet our enrollment targets (400 total patients).

188 Randomization - Phase 2: using a random number generator in the WTH platform, patients will be 1:1  
189 randomized to arm 1 or arm 2, until the target sample size of 200 patients per arm is reached.  
190 Randomization will be performed and recorded in WTH.

191 Chart review - Phase 3: after randomization and in tandem with phase 4 (below), the research  
192 coordinator will perform a chart review to obtain patient demographic and comorbidity data  
193 (hypertension, hyperlipidemia, diabetes, inflammatory bowel disease, obesity, active opiate  
194 prescription). All data will be inputted into and stored in a secured RedCap database. Only key study  
195 staff will have access to the RedCap database, which is stored on a secure firewall-protected server.

196 Intervention - Phase 4: Patients in arm 2 will begin receiving text messages per a pre-determined  
197 protocol starting 7 days prior to the date of scheduled colonoscopy (the text messaging protocol is  
198 attached to this application). Patients in arm 1 and arm 2 will both receive usual care, which includes (1)  
199 bowel preparation instructions that are delivered via mail or through a secure online messaging portal,  
200 (2) a phone call from the endoscopy staff in the week prior to colonoscopy, and (3) the option to call the  
201 endoscopy staff during business hours to have any questions answered on demand.

202 Outcomes data collection - Phase 5: After a patient's scheduled colonoscopy date has passed, the  
203 research coordinator will review the medical record to gather additional data from the endoscopy  
204 procedure. This will include the indication for the procedure, quality of bowel preparation (poor, fair,  
205 good, excellent), and completeness (cecum reached). Procedure status will also be recorded (canceled,  
206 no-show, completed).

207 Statistical Analysis and Manuscript Preparation - Phase 6: The statistical analysis (detailed below) will  
208 commence after completion of outcomes ascertainment for the entire cohort.

209

## 210 **Analysis Plan**

211 Descriptive analysis will include comparison of baseline demographics and major medical comorbidities  
212 between study arms. Continuous and categorical data will be compared using the Wilcoxon Rank-sum  
213 and Chi-squared tests, respectively. An alpha threshold of 0.05 will be used for statistical significance,  
214 with two-tailed testing performed in all instances. For the primary analysis, we will perform a Chi-  
215 squared test of independence to compare the proportion of colonoscopies with good/excellent bowel  
216 preparation between groups. In the secondary analysis, Chi-squared tests of independence will be  
217 performed to compare colonoscopy status (show, no-show, cancelation) as well as bowel preparation  
218 quality (excellent, good, fair, poor) between groups. Finally, among canceled colonoscopies, median lead  
219 time of cancellation will be compared between groups using the Wilcoxon Rank-sum test.

## 220 **Consent**

### 221 ***1. Consent Process***

#### 222 **Overview**

223 We are requesting a waiver of informed consent for this study. The reason for our request is explained  
224 in the Waiver of Consent section. Verbal consent for text messaging will still be obtained from all  
225 participants in the study. Please see the script templates attached to this application.

226

#### 227 **Children and Adolescents**

228 Not applicable. We are only enrolling subjects 18 years of age and older.

229

#### 230 **Adult Subjects Not Competent to Give Consent**

231 We are requesting a waiver of informed consent for this study but patients will still need to verbally opt  
232 in to text messaging. We plan to enroll only those patients who are competent at time of enrollment to  
233 opt-in for themselves.

234

### 235 ***2. Waiver of Consent***

#### 236 **Waiver or Alteration of Informed Consent\***

237 Waiver or alteration of required elements of consent.

238

#### 239 **Minimal Risk\***

240 This study is minimal risk as all participants will be receiving standard clinical care. Colonoscopy is the  
241 standard of care for colorectal cancer screening, and all patients will receive standard bowel preparation  
242 instructions in addition to optional phone communication with endoscopy staff prior to the procedure.  
243 The only research-related activity is the randomization of participants to a text messaging program that  
244 will supplement routine practice when an individual schedules a colonoscopy at our institution. Since  
245 this study is intended to promote the standard of care for colorectal cancer screening, and the receipt of  
246 text messages poses negligible risk to the patient, we believe that waiver of consent is appropriate.

247

#### 248 **Impact on Subject Rights and Welfare\***

249 Participation in the intervention is completely voluntary and subject rights and welfare will not be  
250 adversely affected by the waiver of authorization and consent. Participants randomized to the  
251 intervention arms still need to opt in to text messaging: Arm 1 will receive standard clinical care and Arm  
252 2 will be enrolled into the text-messaging program in addition to standard clinical care. Placement in  
253 either arm for the purposes of research does not adversely affect the rights and welfare of the subjects,  
254 as each arm has the opportunity to engage in colorectal cancer screening, receive bowel preparation  
255 instructions, and communicate with the endoscopy staff over the phone. Randomly assigning patients to  
256 intervention and control does not alter patient's rights any differently than conducting an uncontrolled  
257 pilot study where some patients receive the intervention and some don't. We believe it is appropriate  
258 to obtain waiver of consent because learning the impact of different modalities for improving colorectal  
259 screening has significant potential clinical value for the practice (i.e. significantly increasing the rate of  
260 successful screening and thus decreasing the rate of mortality related to nonuse of screening).

261

#### 262 **Waiver Essential to Research\***

263 The informed consent process itself may influence the outcome of our study, as it would require an  
264 additional phone call by the research coordinate to ask for participation. The purpose of the Way to  
265 Health text messaging program is to provide timely reminders regarding colonoscopy preparation.  
266 Obtaining waiver of consent would allow us to avoid the potential selection/volunteer bias for inclusion  
267 of patients who answer the phone and may be particularly motivated to complete colon cancer  
268 screening. Since our main objective is to understand the potential influence of the text messaging  
269 intervention on colonoscopy show rate and adequate bowel preparation quality among all patients who  
270 agree to text messaging, we believe that obtaining informed consent separately from scheduling would  
271 not allow us to evaluate the impact of the intended intervention, which is text messaging navigation  
272 offered to all patients that agree during scheduling. Additionally, participants will be recruited via verbal  
273 communication when they call our institution call center to schedule their colonoscopy. We believe the  
274 research presents no more than minimal risk of harm to subjects and involves no procedures for which  
275 written consent is normally required outside of the research context.

276

#### 277 **Additional Information to Subjects**



278 Participants randomized to the intervention arms will be informed that this program is voluntary and  
279 that they can stop participating in the program (stop receiving text messages) at any time.

280

281 **Written Statement of Research\***

282 No

283

284 **Risk / Benefit**

285 **Potential Study Risks**

286 The risks associated with this study are no more than minimal. There is the potential risk of breach of  
287 confidentiality involving medical records reviews or text messaging which will be maintained on the Way  
288 to Health platform. We will minimize this risk by using de-identified information whenever possible and  
289 by maintaining all identifiable information on a secure drive and/or in a HIPAA-compliant system (e.g.  
290 REDCap). In addition, all personnel will be held to high standards of upholding confidentiality and  
291 safeguarding patient privacy.

292

293 **Potential Study Benefits**

294 The benefits of this study for participants include a platform that may improve the bowel preparation  
295 experience prior to colonoscopy and increase the likelihood that a colonoscopy will not be hindered by  
296 inadequate preparation or a missed/canceled appointment. This will occur through a set of curated text  
297 messages with timely reminders as well as information with online links and a phone number to improve  
298 accessibility for questions to be answered on a timely basis. It is also possible that the benefits for some  
299 participants will be minimal. However, as mentioned, we believe the risks are also minimal. The control  
300 group is unlikely to directly benefit, as this group will continue to receive usual care. The potential public  
301 health impact of a successful intervention to improve colonoscopy show rates and bowel preparation  
302 quality is significant and could increase the chances of identifying colorectal cancer at an early stage and  
303 reduce the number of repeat colonoscopies and related costs due to inadequate bowel preparation.  
304 Information learned from this study may benefit society through a better understanding of how to  
305 effectively increase the rate of adequate colonoscopies which could increase the rate of colorectal  
306 cancer screening and reduce the rate of mortality.

307

308 **Alternatives to Participation (optional)**

309

310 **Data and Safety Monitoring**

311 The study is minimal risk to participants and therefore the Principal Investigators and study team will  
312 monitor the safety of this study on an ongoing basis.

313

314 **Risk / Benefit Assessment**

315 The risks associated with this study are no more than minimal. Better knowledge on how to increase  
316 colonoscopy show rates and improve bowel preparation quality could potentially address one of the  
317 major barriers to appropriate colorectal cancer screening, which is the second leading cause of cancer  
318 death in the US. This study is designed to test an intervention with demonstrated feasibility and  
319 successful preliminary results in a small QI pilot. For these reasons and those outlined in the above  
320 benefits section, the investigators believe that the potential benefits outweigh the risks of participating  
321 in the study.

322

323

324

325 **Final Protocol**

326 **Automated Text Message Navigation to Improve Outpatient Colonoscopy Show Rate and Bowel**  
327 **Preparation**

328  
329 **\*\*New changes from initial protocol notated in bold, parts removed from initial**  
330 **protocol notated in strikethrough**

331

332 **Brief Description**

333 Outpatient colonoscopy adherence is negatively impacted by poor communication and challenges with  
334 bowel preparation. We plan to perform a randomized controlled trial at the Pennsylvania Presbyterian  
335 Medical Center to (1) provide text message-based educational and reminder messages to patients  
336 regarding a scheduled colonoscopy, and (2) evaluate the impact of the texting intervention on  
337 colonoscopy show rate and bowel preparation.

338

339 **Protocol**

340 **Abstract**

341 Colonoscopy is an effective screening technique for colorectal cancer (CRC) prevention, but many  
342 patients either do not show up or have poor bowel preparation for the procedure. We plan to evaluate  
343 the impact and feasibility of a text message-based program to provide patients with timely educational  
344 and reminder messages regarding their upcoming colonoscopy and bowel preparation process. In this  
345 pragmatic randomized controlled trial, we aim to (1) to provide text message-based educational and  
346 reminder messages to patients or support partners regarding a scheduled colonoscopy, and (2) to  
347 evaluate the impact of the texting intervention on colonoscopy show rate and bowel preparation. We  
348 will include patients who are scheduled for outpatient colonoscopy at the Pennsylvania Presbyterian  
349 Medical Center. After enrollment, patients will be randomized 1:1 to usual care (arm 1) or the text  
350 message-based intervention (arm 2, one week in duration). We will measure colonoscopy show rate  
351 with good/excellent bowel preparation as the primary outcome.

352

353 **Objectives**

354 **Overall objectives**

355 The specific aims of the study are to (1) to provide text message-based educational and reminder  
356 messages to patients or support partners regarding a scheduled colonoscopy, and (2) to evaluate the  
357 impact of the texting intervention on colonoscopy show rate and bowel preparation.

358

359 **Primary outcome variable(s)**

360 The primary outcome of the study will be colonoscopy show rate with good/excellent bowel preparation  
361 (binary).

### 362 **Secondary outcome variable(s)**

363 Secondary outcomes of the study will include colonoscopy show rate, bowel preparation quality (rescue,  
364 poor, fair, **adequate**, good, excellent; **we will also collect Boston Bowel Prep Score if available [scale 0-**  
365 **9]**), colonoscopy cancellation rate, timing of advance cancellation notification (days), **colonoscopy**  
366 **reschedule rate**, and colonoscopy appointment no-show rate. **A colonoscopy “show” will be defined as**  
367 **a patient who attends their originally scheduled colonoscopy appointment. A “cancellation” will be**  
368 **defined as an appointment that is canceled at least one day prior to the originally scheduled**  
369 **colonoscopy appointment date. A “reschedule” will be defined as an appointment that is canceled**  
370 **and rescheduled (for a future date) on the same day, at least one day prior to the originally scheduled**  
371 **colonoscopy appointment date. Finally, as an additional secondary outcome, we will also collect the**  
372 **proportion of patients who opt out of the texting program in the late phase of enrollment (described**  
373 **below).**

374

### 375 **Background**

376 Colorectal cancer (CRC) is the second leading cause of cancer death in the US, yet there are effective  
377 screening and treatment strategies that allow for early detection and treatment. CRC screening is  
378 recommended for all individuals aged 50-75, which could include stool testing or colonoscopy, but  
379 national rates are still suboptimal at 59-65%. Colonoscopy is an essential component of CRC screening,  
380 as it is also required if stool testing is positive. However, colonoscopy requires a complex process to  
381 identify an escort, purchase the preparation, take a day off from work, adhere to a clear liquid diet, and  
382 complete the split-dose preparation as recommended. This results in a significant no-show and  
383 cancellation rate, along with suboptimal preparation quality, which can lead to non-adherence and  
384 incomplete screening.

385 Current approaches to engaging patients include having nurses call patients before the procedure or  
386 patient navigators. However, it is often difficult to get patients on the phone, and these interventions  
387 can be costly, making it less scalable for clinical practices. Other interventions such as videos or mobile  
388 apps have been limited by poor user experience or limited engagement with the patient. There is an  
389 opportunity to leverage an automated text message navigation intervention using the Way to Health  
390 (WTH) platform to improve patient engagement prior to colonoscopy completion. The WTH platform is a  
391 Penn Medicine platform that is hosted on site at the University of Pennsylvania. The platform allows  
392 custom text messages to automatically be sent to patients, in addition to bidirectional message  
393 capabilities. WTH is protected by a secure firewall and is a HIPAA compliant platform.

394 In the past year, our team conducted a quality improvement pilot initiative using WTH that tested the  
395 feasibility and impact of a one-week text messaging protocol for patients who were scheduled for  
396 outpatient colonoscopy. The text messages sent to patients contained information about the  
397 preparation process and instructions, expectations about the procedure, and reminders about location  
398 and timing. Among the 21 patients enrolled in the pilot, we found high user acceptability and higher

399 colonoscopy show rates as compared to baseline values at PPMC (90% versus ~50%). As such we believe  
400 that the texting intervention is feasible for testing in the context of a randomized controlled trial.

401

## 402 **Study Design**

### 403 Design

404 We will perform a pragmatic randomized controlled trial evaluating the impact of the text message-  
405 based intervention (arm 2) as compared to usual care alone (arm 1). Patient enrollment will **proceed**  
406 **through two pathways (early phase and late phase). In the early phase, 250 patients will be enrolled**  
407 **through** ~~be performed with assistance from the call center at the Pennsylvania Presbyterian Medical~~  
408 ~~Center (PPMC), and/or through phone calls from a clinical research coordinator, using a script pre-~~  
409 **approved by the University of Pennsylvania Institutional Review Board.** After enrollment, patients will  
410 be randomized 1:1 to the arms listed above through the Way to Health platform. Although patients in  
411 arm 2 may be enrolled **more than one weeks or months** in advance of their colonoscopy, they will only  
412 receive intervention text messages in the 7 days prior to the scheduled colonoscopy, **in addition to two**  
413 **text messages at the time of enrollment explaining the texting program.** Usual care consists of a phone  
414 call from the PPMC endoscopy staff in the week prior to colonoscopy, if the patient is able to be  
415 reached. Patients are also given the endoscopy phone number, and may call to speak to staff if they  
416 have specific questions about their colonoscopy or need to reschedule. **In the late phase, an additional**  
417 **500 patients will be automatically enrolled in the Way to Health system using verified cell phone**  
418 **numbers from the electronic medical record system, where they will be randomized in a 1:1 ratio to**  
419 **the study arms in variable blocks of 8 and 4. Patients in arm 2 will receive two enrollment text**  
420 **messages explaining the texting program and providing the opportunity to opt out (by replying with**  
421 **the text STOP).** A detailed outline of ~~the~~ study design can be found in the procedures sections.

422

### 423 **Study duration**

424 The duration of participation for patients in the intervention will be from the time of enrollment to the  
425 date of scheduled colonoscopy. However, the patient will only receive intervention text messages in the  
426 week prior to the scheduled colonoscopy, **with the exception of the two enrollment messages in the**  
427 **late phase.** We will plan to recruit patients from November 2018 through ~~January~~ **June 2019.** We  
428 estimate that the study will be completed by ~~March~~ **August 2019.**

429

### 430 **Resources necessary for human research protection**

431 Describe research staff and justify that the staff are adequate in number and qualifications to conduct  
432 the research. Describe how you will ensure that all staff assisting with the research are adequately  
433 informed about the protocol and their research related duties. Please allow adequate time for the  
434 researchers to conduct and complete the research. Please confirm that there are adequate facilities for  
435 the research.

436

437 The project will take place at the Pennsylvania Presbyterian Medical Center (PPMC) at the University of  
438 Pennsylvania (UPENN). The team includes investigators experienced in clinical medicine, health behavior  
439 interventions, clinical trials, behavioral economics, and program evaluation. This study will be led by Dr.  
440 Shivan Mehta, MD, MBA, MSHP, Assistant Professor of Medicine and Associate Chief Innovation Officer  
441 for Penn Medicine. This study will be supported on a secure web portal on the Way to Health platform,  
442 modified to the specifications of this study. Additional study staff include a gastroenterology fellow, a  
443 **clinical research coordinator**, a medical student, key PPMC endoscopy staff, and quality improvement  
444 specialists. Regular group meetings will be held at pivotal points in the trial in order to ensure  
445 compliance with protocol and research-related duties.

446

#### 447 **Characteristics of the Study Population**

448 Target population

449 Eligibility Criteria: Patients will be eligible for study inclusion if they are age 18-85 years and are  
450 scheduled for outpatient colonoscopy to be completed at the PPMC outpatient endoscopy center. We  
451 will exclude patients if there are fewer than ~~14~~ 10 days from time of scheduling to the scheduled date of  
452 colonoscopy. The target enrollment sample size is ~~750~~ 400 patients— ~~375~~ 200 in arm 1 (usual care) and  
453 ~~375~~ 200 in arm 2 (usual care plus texting intervention). This number is based **in part** on sample size  
454 calculations using data from a previous pilot, which suggests that a total sample size of ~~750~~ 200 patients  
455 will have greater than 80% power to detect a ~~10~~ 15% difference in the primary outcome. **We also chose**  
456 **a larger sample size to account for the fact that patients may opt out of the text messages in the late**  
457 **phase of enrollment, which would likely decrease the effect size between arms.**

458

459 Subjects enrolled by Penn Researchers

460 **750** 400

461

462 Subjects enrolled by Collaborating Researchers

463 0

464

#### 465 **Accrual**

466 Participants in the study will be planned for outpatient colonoscopy at the Pennsylvania Presbyterian  
467 Medical Center (PPMC). Once a patient is confirmed to meet eligibility criteria, patient enrollment will  
468 ~~be performed~~ **proceed based on one of two pathways (early and late phase). In the early phase (first**  
469 **250 patients), enrollment will be performed with assistance from the call center at PPMC, and/or**  
470 ~~through phone calls from a clinical research coordinator. When patients have a physician order for a~~  
471 ~~colonoscopy, the patient must contact the call center in order to schedule the colonoscopy. The call~~  
472 ~~center staff have agreed to discuss the research project and enroll patients using a script to be approved~~  
473 ~~by the IRB. Similarly,~~ **The research coordinator will call newly scheduled patients to discuss the**

474 research project and enroll patients using a script to approved by the University of Pennsylvania IRB.  
475 If patients are scheduled for colonoscopy in person while at the office, they will receive an  
476 informational flyer about the study that gives them the opportunity to contact a study team member  
477 for additional information or to enroll. It also informs them that someone from the study may contact  
478 them directly about participating. After enrollment, patients will be 1:1 randomized to arm 1 or arm 2  
479 using the Way to Health platform.

480

481 In the late phase (additional 500 patients), patients with upcoming colonoscopy appointments will be  
482 screened for eligibility as per the selection criteria. As in the early phase, if patients are scheduled for  
483 colonoscopy in person while at the office, they will receive an informational flyer about the study that  
484 lets them know they may be contacted by text message about their upcoming procedure. Those who  
485 qualify will have their validated cell phone numbers imported into Way to Health, where they will  
486 subsequently be randomized. Those in the intervention arm will receive two enrollment messages  
487 describing the study and providing the opportunity to opt out (by replying with the text STOP). Of  
488 note, if a patient in the late phases chooses to opt out and not receive the texting intervention, their  
489 data will still be analyzed in the intervention group (as an intention-to-treat approach). Importantly,  
490 we are requesting a waiver of consent for several reasons: (1) the study presents no more than minimal  
491 risk of harm to participants, (2) the patients who are randomized to either arm will not be deprived of  
492 any standard care available in the status quo and thus the study will not violate their rights or welfare,  
493 (3) the study could not be practicably completed without such a waiver, as the scheduling process is  
494 handled over the phone by call center staff, and (4) requiring standard informed consent would require  
495 an additional touchpoint by the research coordinator and the consent process would preclude us from  
496 evaluating the intended intervention by introducing selection bias and altering the intervention that  
497 patients receive.

498

499 Key inclusion criteria

500 Eligibility Criteria: Patients between ages 18 and 85 years who are scheduled for outpatient colonoscopy  
501 at PPMC and have a cell phone **with enabled text messaging capability**.

502

503 Key exclusion criteria

504 Exclusion Criteria: Patients will be excluded if there are fewer than **14** ~~10~~ days between the time of  
505 enrollment and time of scheduled colonoscopy. This will ensure **the clinical research coordinator has**  
506 **sufficient time to reach newly scheduled patients, and** that patients randomized to arm 2 will have  
507 sufficient time to receive the full text message intervention. Patients will also be excluded if they **are**  
508 **non-English speaking requiring a translator, or if they are not the primary individual receiving the text**  
509 **messages. Finally, patients will be excluded if they** do not meet all of the inclusion criteria, or if they  
510 refuse participation in text messaging.

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515

516 **Procedures**

517 Screening – Phase 1: **As above, patients will be screened and enrolled through one of two pathways**  
518 **(early and late phase). In the early phase (first 250 patients),** ~~Patients who have a physician order for a~~  
519 ~~colonoscopy will call the PPMC call center in order to schedule their procedure. At this time, the call~~  
520 ~~center staff will screen the patient for eligibility (age criteria and text messaging ability) and will explain~~  
521 ~~the details of the study following a pre-determined script. Patients who agree to participate in the study~~  
522 ~~will have their cell phone number recorded. A list of these patients will be forward to the clinical~~  
523 ~~research coordinator on a weekly regular basis, who will confirm patient eligibility and then manually~~  
524 ~~enter patients into the WTH platform for randomization. Alternatively, a PPMC practice manager will~~  
525 **forward a list of scheduled colonoscopies to the clinical research coordinator (CRC) on a regular basis.**  
526 **If patients are scheduled for colonoscopy in person while at the office, they will receive an**  
527 **informational flyer about the study that gives them the opportunity to contact a study team member**  
528 **for additional information or to enroll. It also informs them that someone from the study may contact**  
529 **them directly about participating. The CRC will screen for patients for eligibility and make up to 3**  
530 **phone call attempts to reach the patient. Once on the phone, the CRC will explain the details of the**  
531 **study using a script approved by the IRB and enter patients directly into the WTH platform for**  
532 **randomization. In the late phase (additional 500 patients), patients will be screened for eligibility**  
533 **through the same process as in the early phase. If they are scheduled for colonoscopy in person while**  
534 **at the office, they will also receive an informational flyer about the study that lets them know they**  
535 **may be contacted by text message about their upcoming procedure. For eligible patients, the CRC will**  
536 **then manually enter the validated patient cell phone number from the electronic medical record**  
537 **system into WTH. Randomization will then occur as described below, and intervention arm patients**  
538 **will receive two enrollment messages. These messages will describe the texting program and provide**  
539 **the opportunity for patients to opt out (by texting the word STOP). Of note, phone numbers will be**  
540 **confirmed to represent cell phones by using a publicly-available lookup utility. Importantly, patients**  
541 **who opt out will still be included in the intervention arm as an intention-to-treat analysis. Based on**  
542 **our experience with the QI pilot described above, we estimate needing to screen between 500 and**  
543 **approximately 1,000 600 patients to meet our enrollment targets (750 400 total patients).**

544 Randomization - Phase 2: **In the early phase,** using a random number generator in the WTH platform,  
545 patients will be 1:1 randomized to arm 1 or arm 2. **Beginning in the late phase of enrollment, patients ,**  
546 ~~until the target will be randomized to arm 1 or arm 2 in a 1:1 ratio in variable blocks of 8 and 4 using~~  
547 **the WTH platform, until the target sample size of 375 patients per arm is reached.** ~~sample size of 200~~  
548 ~~patients per arm is reached. Randomization will be performed and recorded in WTH.~~

549 Chart review - Phase 3: after randomization and in tandem with phase 4 (below), the research  
550 coordinator will perform a chart review to obtain patient demographic and comorbidity data  
551 (hypertension, hyperlipidemia, diabetes, inflammatory bowel disease, obesity, active opiate  
552 prescription). **We will also collect data on the number of patients opting out in the late phase of**  
553 **enrollment, as well as data on nursing phone calls which are performed as a component of usual care**



554 **(not called, called but could not reach patient, called and spoke with patient)**. All data will be inputted  
555 into and stored in a secured RedCap database. Only key study staff will have access to the RedCap  
556 database, which is stored on a secure firewall-protected server.

557 Intervention - Phase 4: Patients in arm 2 will begin receiving text messages per a pre-determined  
558 protocol starting 7 days prior to the date of scheduled colonoscopy (the text messaging protocol is  
559 attached to this application). **Of note, if a patient in arm 2 cancels or reschedules their colonoscopy**  
560 **after randomization, they will not receive any additional protocol text messages as part of this trial.**  
561 Patients in arm 1 and arm 2 will both receive usual care, which includes (1) bowel preparation  
562 instructions that are delivered via mail or through a secure online messaging portal, (2) a phone call  
563 from the endoscopy staff in the week prior to colonoscopy, and (3) the option to call the endoscopy staff  
564 during business hours to have any questions answered on demand.

565 Outcomes data collection - Phase 5: After a patient's scheduled colonoscopy date has passed, the  
566 research coordinator will review the medical record to gather additional data from the endoscopy  
567 procedure. This will include the indication for the procedure, quality of bowel preparation (**rescue**, poor,  
568 fair, **adequate**, good, excellent; **Boston Bowel Prep Score will also be collected if recorded**), and  
569 completeness (cecum reached). Procedure status will also be recorded (canceled, no-show,  
570 **rescheduled**, completed). **If the procedure was canceled, the cancellation lead time (in days) prior to**  
571 **scheduled colonoscopy will be recorded.**

572 Statistical Analysis and Manuscript Preparation - Phase 6: The statistical analysis (detailed below) will  
573 commence after completion of outcomes ascertainment for the entire cohort.

574

## 575 **Analysis Plan**

576 Descriptive analysis will include comparison of baseline demographics and major medical comorbidities  
577 between study arms. Continuous and categorical data will be compared using the Wilcoxon Rank-sum  
578 and Chi-squared tests, respectively. An alpha threshold of 0.05 will be used for statistical significance,  
579 with two-tailed testing performed in all instances. For the primary analysis, we will perform a Chi-  
580 squared test of independence to compare the proportion of colonoscopies with good/excellent bowel  
581 preparation between groups. In the secondary analysis, Chi-squared tests of independence will be  
582 performed to compare colonoscopy status (show, no-show, **reschedule**, cancellation) as well as bowel  
583 preparation quality (excellent, good, **adequate**, fair, poor) between groups. ~~Finally, a~~ Among canceled  
584 colonoscopies, median lead time of cancellation will be compared between groups using the Wilcoxon  
585 Rank-sum test. **Finally, for both primary and secondary analyses, we will consider multivariable**  
586 **regression modeling to adjust for imbalances in possible confounders, if present despite**  
587 **randomization.**

## 588 **Consent**

### 589 **1. Consent Process**

#### 590 **Overview**

591 We are requesting a waiver of informed consent for this study. The reason for our request is explained  
592 in the Waiver of Consent section. Verbal consent for text messaging will still be obtained from all  
593 participants in the study. Please see the script templates attached to this application.

594

#### 595 **Children and Adolescents**

596 Not applicable. We are only enrolling subjects 18 years of age and older.

597

#### 598 **Adult Subjects Not Competent to Give Consent**

599 We are requesting a waiver of informed consent for this study but patients will still need to verbally opt  
600 in to text messaging. We plan to enroll only those patients who are competent at time of enrollment to  
601 opt-in for themselves.

602

#### 603 **2. Waiver of Consent**

##### 604 **Waiver or Alteration of Informed Consent\***

605 Waiver or alteration of required elements of consent.

606

##### 607 **Minimal Risk\***

608 This study is minimal risk as all participants will be receiving standard clinical care. Colonoscopy is the  
609 standard of care for colorectal cancer screening, and all patients will receive standard bowel preparation  
610 instructions in addition to optional phone communication with endoscopy staff prior to the procedure.

611 The only research-related activity is the randomization of participants to a text messaging program that  
612 will supplement routine practice when an individual schedules a colonoscopy at our institution. Since  
613 this study is intended to promote the standard of care for colorectal cancer screening, and the receipt of  
614 text messages poses negligible risk to the patient, we believe that waiver of consent is appropriate.

615

##### 616 **Impact on Subject Rights and Welfare\***

617 Participation in the intervention is completely voluntary and subject rights and welfare will not be  
618 adversely affected by the waiver of authorization and consent. Participants randomized to the  
619 intervention arms still need to opt in to text messaging: Arm 1 will receive standard clinical care and Arm  
620 2 will be enrolled into the text-messaging program in addition to standard clinical care. Placement in  
621 either arm for the purposes of research does not adversely affect the rights and welfare of the subjects,  
622 as each arm has the opportunity to engage in colorectal cancer screening, receive bowel preparation  
623 instructions, and communicate with the endoscopy staff over the phone. Randomly assigning patients to  
624 intervention and control does not alter patient's rights any differently than conducting an uncontrolled  
625 pilot study where some patients receive the intervention and some don't. We believe it is appropriate

626 to obtain waiver of consent because learning the impact of different modalities for improving colorectal  
627 screening has significant potential clinical value for the practice (i.e. significantly increasing the rate of  
628 successful screening and thus decreasing the rate of mortality related to nonuse of screening).

629

#### 630 **Waiver Essential to Research\***

631 The informed consent process itself may influence the outcome of our study, as it would require an  
632 additional phone call by the research coordinate to ask for participation. The purpose of the Way to  
633 Health text messaging program is to provide timely reminders regarding colonoscopy preparation.  
634 Obtaining waiver of consent would allow us to avoid the potential selection/volunteer bias for inclusion  
635 of patients who answer the phone and may be particularly motivated to complete colon cancer  
636 screening. Since our main objective is to understand the potential influence of the text messaging  
637 intervention on colonoscopy show rate and adequate bowel preparation quality among all patients who  
638 agree to text messaging, we believe that obtaining informed consent separately from scheduling would  
639 not allow us to evaluate the impact of the intended intervention, which is text messaging navigation  
640 offered to all patients that agree during scheduling. Additionally, participants will be recruited via verbal  
641 communication when they call our institution call center to schedule their colonoscopy. We believe the  
642 research presents no more than minimal risk of harm to subjects and involves no procedures for which  
643 written consent is normally required outside of the research context.

644

#### 645 **Additional Information to Subjects**

646 Participants randomized to the intervention arms will be informed that this program is voluntary and  
647 that they can stop participating in the program (stop receiving text messages) at any time.

648

#### 649 **Written Statement of Research\***

650 No

651

#### 652 **Risk / Benefit**

##### 653 **Potential Study Risks**

654 The risks associated with this study are no more than minimal. There is the potential risk of breach of  
655 confidentiality involving medical records reviews or text messaging which will be maintained on the Way  
656 to Health platform. We will minimize this risk by using de-identified information whenever possible and  
657 by maintaining all identifiable information on a secure drive and/or in a HIPAA-compliant system (e.g.  
658 REDCap). In addition, all personnel will be held to high standards of upholding confidentiality and  
659 safeguarding patient privacy.

660

##### 661 **Potential Study Benefits**

662 The benefits of this study for participants include a platform that may improve the bowel preparation  
663 experience prior to colonoscopy and increase the likelihood that a colonoscopy will not be hindered by  
664 inadequate preparation or a missed/canceled appointment. This will occur through a set of curated text  
665 messages with timely reminders as well as information with online links and a phone number to improve  
666 accessibility for questions to be answered on a timely basis. It is also possible that the benefits for some  
667 participants will be minimal. However, as mentioned, we believe the risks are also minimal. The control  
668 group is unlikely to directly benefit, as this group will continue to receive usual care. The potential public  
669 health impact of a successful intervention to improve colonoscopy show rates and bowel preparation  
670 quality is significant and could increase the chances of identifying colorectal cancer at an early stage and  
671 reduce the number of repeat colonoscopies and related costs due to inadequate bowel preparation.  
672 Information learned from this study may benefit society through a better understanding of how to  
673 effectively increase the rate of adequate colonoscopies which could increase the rate of colorectal  
674 cancer screening and reduce the rate of mortality.

675

#### 676 **Alternatives to Participation (optional)**

677

#### 678 **Data and Safety Monitoring**

679 The study is minimal risk to participants and therefore the Principal Investigators and study team will  
680 monitor the safety of this study on an ongoing basis.

681

#### 682 **Risk / Benefit Assessment**

683 The risks associated with this study are no more than minimal. Better knowledge on how to increase  
684 colonoscopy show rates and improve bowel preparation quality could potentially address one of the  
685 major barriers to appropriate colorectal cancer screening, which is the second leading cause of cancer  
686 death in the US. This study is designed to test an intervention with demonstrated feasibility and  
687 successful preliminary results in a small QI pilot. For these reasons and those outlined in the above  
688 benefits section, the investigators believe that the potential benefits outweigh the risks of participating  
689 in the study.

## Summary of Protocol Changes

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691

692 **Protocol:** Automated Text Message Navigation to Improve Outpatient Colonoscopy Show Rate and Bowel Preparation  
693 **University of Pennsylvania Principal Investigator:** Shivan Mehta, MD

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Date of Submission	Description of Modification	Rationale for Modification	Approval date
9/11/18	Initial submission		10/8/2018
10/22/18	Modification: - add staff (CRC) - add call center script		10/23/2018
11/14/18	Modification: - add recruitment by CRC & call script - change exclusion (from 10 to 14 days)		11/15/2018
12/19/18	Modification: - add patient recruitment flyer - modify CRC call script		12/19/2018
1/2/2019	Modification: - modify CRC call script - modify "welcome text" message for pts in intervention arm - modify inclusion/exclusion criteria - add description of procedure if arm 2 patient cancels or reschedules colonoscopy - add lead time of cancellation as an outcome measure (in days)		
4/4/2019	Modification: - modify sample size target - distinguish early and late phase enrollment		



## 696 Initial Statistical Analysis Plan

697

698 The target enrollment sample size is 400 patients—200 in arm 1 (usual care) and 200 in arm 2 (usual care  
699 plus texting intervention). This number is based on sample size calculations using data from a previous  
700 pilot, which suggests that a total sample size of 200 patients will have greater than 80% power to detect a  
701 15% difference in the primary outcome.

702 Descriptive analysis will include comparison of baseline demographics and major medical comorbidities  
703 between study arms. Continuous and categorical data will be compared using the Wilcoxon Rank-sum and  
704 Chi-squared tests, respectively. An alpha threshold of 0.05 will be used for statistical significance, with  
705 two-tailed testing performed in all instances. For the primary analysis, we will perform a Chi-squared test  
706 of independence to compare the proportion of colonoscopies with good/excellent bowel preparation  
707 between groups. In the secondary analysis, Chi-squared tests of independence will be performed to  
708 compare colonoscopy status (show, no-show, cancelation) as well as bowel preparation quality (excellent,  
709 good, fair, poor) between groups. Finally, among canceled colonoscopies, median lead time of cancellation  
710 will be compared between groups using the Wilcoxon Rank-sum test.

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726 Final Statistical Analysis Plan

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728 **\*\*New changes from initial protocol notated in bold, parts removed from initial**  
729 **protocol notated in strikethrough**

730

731 The target enrollment sample size is **750** ~~400~~ patients—~~375~~ ~~200~~ in arm 1 (usual care) and ~~375~~ ~~200~~ in arm 2  
732 (usual care plus texting intervention). This number is based **in part** on sample size calculations using data  
733 from a previous pilot, which suggests that a total sample size of ~~750~~ ~~200~~ patients will have greater than  
734 80% power to detect a ~~10~~ ~~±5~~% difference in the primary outcome. **We also chose a larger sample size to**  
735 **account for the fact that some patients enrolled in arm 2 may opt out of receiving text messages, which**  
736 **would likely decrease the effect size between arms.**

737 Descriptive analysis will include comparison of baseline demographics and major medical comorbidities  
738 between study arms. Continuous and categorical data will be compared using the Wilcoxon Rank-sum and  
739 Chi-squared tests, respectively. An alpha threshold of 0.05 will be used for statistical significance, with  
740 two-tailed testing performed in all instances. For the primary analysis, we will perform a Chi-squared test  
741 of independence to compare the proportion of colonoscopies with good/excellent bowel preparation  
742 between groups. In the secondary analysis, Chi-squared tests of independence will be performed to  
743 compare colonoscopy status (show, no-show, **reschedule**, cancelation) as well as bowel preparation  
744 quality (excellent, good, **adequate**, fair, poor) between groups. ~~Finally,~~ ~~a~~ Among canceled colonoscopies,  
745 median lead time of cancellation will be compared between groups using the Wilcoxon Rank-sum test.  
746 **Finally, for both primary and secondary analyses, we will consider multivariable regression modeling to**  
747 **adjust for imbalances in possible confounders, if present despite randomization.**

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754 **Summary of Statistical Analysis Plan Modifications**

- 755
- 756 - Sample size adjusted
  - 757 - Additional details regarding secondary outcomes
  - 758 - Added possibility of regression analyses if imbalances in potential confounders are noted
- 759

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## Appendix A: Intervention Text Messaging Schedule and Content

Timing	Message
Upon enrollment	Congrats <name> on scheduling your colonoscopy on <date> with <provider>! We would like to offer you a texting program to guide you through the process. Just so you have it, here is an online link to the prep instructions: <a href="http://bit.ly/2nHjpbK">http://bit.ly/2nHjpbK</a>
Day -7: 8AM	Hi <name>, only one week before your colonoscopy! We will be in touch this week to guide you through the process. If you take any blood thinners (like warfarin), make sure you have discussed this with your prescribing doctor. Some patients may need to stop these before the procedure.
Day -6: 8AM	Hello, <name>! Hopefully you received a paper copy of your colonoscopy prep instructions. Just in case, here is a link to the same instructions online: <a href="http://bit.ly/2nHjpbK">http://bit.ly/2nHjpbK</a>
Day -5: 8AM	Hello <name>, don't forget to pick up your prep materials from the local pharmacy, which includes MiraLAX, Dulcolax, and Gatorade (or Crystal Light or Pedialyte if you have diabetes). This info is in the instructions at this link: <a href="http://bit.ly/2nHjpbK">http://bit.ly/2nHjpbK</a>
Day -4: 8AM	Good morning, <name>! Only 4 days to go until your procedure! If you have any questions about the colonoscopy, please call 215-662-9131 between 8AM and 6PM.
Day -3: 8AM	Hi <name>, make sure you have someone to take you home after your colonoscopy. Plan to arrive one hour before your procedure time. Penn Endoscopy is located at the CUPP Building, 51 N. 39th St., Phila. PA. Here is a link: <a href="https://bit.ly/2rWQRwO">https://bit.ly/2rWQRwO</a>
Day -2: 8AM	<name>, your colonoscopy is in 2 days! Today, avoid high-fiber foods like fruits, vegetables, and seeds. Starting tomorrow morning, you should have only clear liquids until your procedure is complete.
Day -1: 8AM	<name>, you have already come so far! Continue a clear liquid diet today (liquids you can see through with light colors). Remember, no solid foods! The next step will be to take 4 Dulcolax pills at 4PM.
Day -1: 4PM	It is time to take the 4 Dulcolax pills and mix the MiraLAX with the Gatorade (or Crystal Light or Pedialyte). At 5PM, you should start drinking the first half gallon of your prep. If you feel nauseated, you can always slow down to help tolerate it. You can do it!
Day -1: 6PM	Good job! Start drinking the second half gallon of the prep 6 hours before your scheduled arrival time. Try to drink every last drop to get the best prep you possibly can!

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765 **Appendix B: Telephone Consent Script**

766

767 **Caller:** Our department is conducting a trial to improve the colonoscopy preparation experience for  
768 patients by sending a series of eight text messages in the week prior to the procedure. The messages  
769 contain information and reminders about the preparation process. Participation is completely voluntary. If  
770 you agree, you will randomly be selected to either receive the text messages or not.

771

772 Would you be willing to participate in this research study?

773

774 [If no, thank for time]

775

776 [If yes, continue]

777

778 I just want to confirm that we have the correct cell phone number for you... (confirm number)

779

780 Do you have any questions regarding your participation?

781

782 [If no, thank for time]

783

784 [If yes, address questions, and thank for time]

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