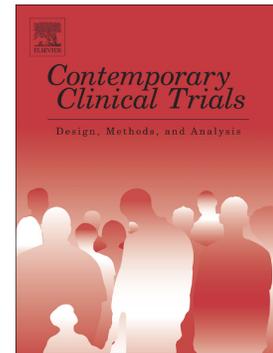


Accepted Manuscript

Rationale and design of the ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus (ENGAGE-DM) pragmatic trial

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PII: S1551-7144(17)30128-3
DOI: doi: [10.1016/j.cct.2017.05.014](https://doi.org/10.1016/j.cct.2017.05.014)
Reference: CONCLI 1568
To appear in: *Contemporary Clinical Trials*
Received date: 27 February 2017
Revised date: 26 May 2017
Accepted date: 29 May 2017

Please cite this article as: Julie C. Lauffenburger, Jennifer Lewey, Saira Jan, Gina Nanchanatt, Sagar Makanji, Christina A. Ferro, John Sheehan, Eric Wittbrodt, Kyle Morawski, Jessica Lee, Roya Ghazinouri, Nitesh K. Choudhry , Rationale and design of the ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus (ENGAGE-DM) pragmatic trial. The address for the corresponding author was captured as affiliation for all authors. Please check if appropriate. Concli(2017), doi: [10.1016/j.cct.2017.05.014](https://doi.org/10.1016/j.cct.2017.05.014)

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Rationale and design of the ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus (ENGAGE-DM) pragmatic trial

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Manuscript Word Count: 3,224 (excluding title page, abstract, tables/figures, references)

Abstract Word Count: 208

Introduction Word Count: 433

Discussion Word Count: 484

Source of Support: This research was supported by unrestricted funding for this project paid to Brigham and Women's Hospital from AstraZeneca.

Conflicts of Interest: At the time of this writing, John Sheehan was an employee of AstraZeneca. Eric Wittbrodt is an employee of AstraZeneca. There are no other relevant conflicts to disclose.

ABSTRACT

Background: Poor glycemic control among patients with diabetes may stem from poor medication and lifestyle adherence or a failure to appropriately intensify therapy. A patient-centered approach could discern the most likely possibility and would then, as appropriate, address patient barriers to non-adherence (using behavioral interviewing methods such as motivational interviewing) or help facilitate choices among treatment augmentation options (using methods such as shared decision-making).

Objective: To test the impact of a novel telephone-based patient-centered intervention on glycemic control for patients with poorly-controlled diabetes.

Methods/design: ENGAGE-DM (ENhancing outcomes through Goal Assessment and Generating Engagement in Dialyzed Mellitus) is a pragmatic trial of patients with poorly-controlled diabetes receiving treatment with an oral hypoglycemic agent. We randomized 1,400 patients in a large health insurer to intervention or usual care. The intervention is delivered over the telephone by a pharmacist and consists of a 2-step process that integrates brief negotiated interviewing and shared decision-making to identify patient-concordant goals and options for enhancing patients' diabetes management. The trial's primary outcome is disease control, assessed using glycosylated hemoglobin values. Secondary outcomes include medication adherence measures, assessed using pharmacy claims data.

Conclusions: This trial will determine whether a novel highly-scalable patient engagement strategy improves disease control and adherence to medications among individuals with poorly-controlled diabetes.

Key Words: Diabetes; pragmatic trial; medication adherence; behavioral intervention;
clinical pharmacist

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INTRODUCTION

Despite the availability of numerous oral hypoglycemic agents to treat individuals with type 2 diabetes (T2D), more than 40% of patients on these agents do not achieve glycosylated hemoglobin (A1C) goals, placing them at substantial risk for potentially avoidable morbidity and mortality.^{1,2} In these circumstances, it is unclear whether suboptimal glycemic control stems from patient non-adherence to their prescribed medications, the failure of providers to appropriately intensify therapy when indicated (i.e., clinical inertia), the unwillingness of patients to initiate clinician-recommended treatments or a combination of these factors.^{3,4} Because providers often cannot easily distinguish these barriers in the context of clinical encounters, more effective patient-centered approaches are needed.^{5,6} However, eliciting this type of information from patients can be challenging, especially in ways that are broadly scalable and efficient.

One promising strategy for eliciting patient-specific barriers and preferences is brief negotiated interviewing, which is a semi-structured patient-oriented approach to counseling.⁷⁻⁹ Brief negotiated interviewing takes the form of short counseling sessions that incorporate feedback, advice, and motivational enhancement techniques.⁷ It has shown promising results in improving medication adherence and decreasing unhealthy behaviors such as alcohol abuse.^{7,8,10,11} In the case of poorly-controlled diabetes, brief negotiated interviewing could be used to identify, in a structured and therefore reproducible manner, whether non-adherence or the need for treatment intensification constitute an individual patient's primary barrier to glycemic control. If non-adherence is identified as a potential barrier, brief negotiated interviewing may also be efficient at engaging patients in conversations about specific adherence barriers.

In the case of patients who require treatment intensification, brief negotiated interviewing could be linked to other patient-centered approaches that elicit specific preferences about treatments, such as shared decision-making. Shared decision-making is a collaborative process of decision-making between patients and their providers that takes into account the patient's values and preferences and clinical evidence.¹² There is much evidence that supports its ability to help patients make treatment choices consistent with their own goals.¹²⁻¹⁴ In the case of diabetes treatment intensification, this approach could be used to identify patient preferences between different hypoglycemic treatments which differ in their side effect profiles, costs and other important characteristics.

Even though brief negotiated interviewing and shared decision-making complement one another as patient engagement techniques, no studies have attempted to combine these two approaches. In addition, few studies have delivered either of these behavioral techniques in ways that could be scaled to large populations of patients, such as over the telephone, even though health insurers routinely use telephonic outreach to members. To address these knowledge gaps, we launched the ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus (ENGAGE-DM) pragmatic trial.

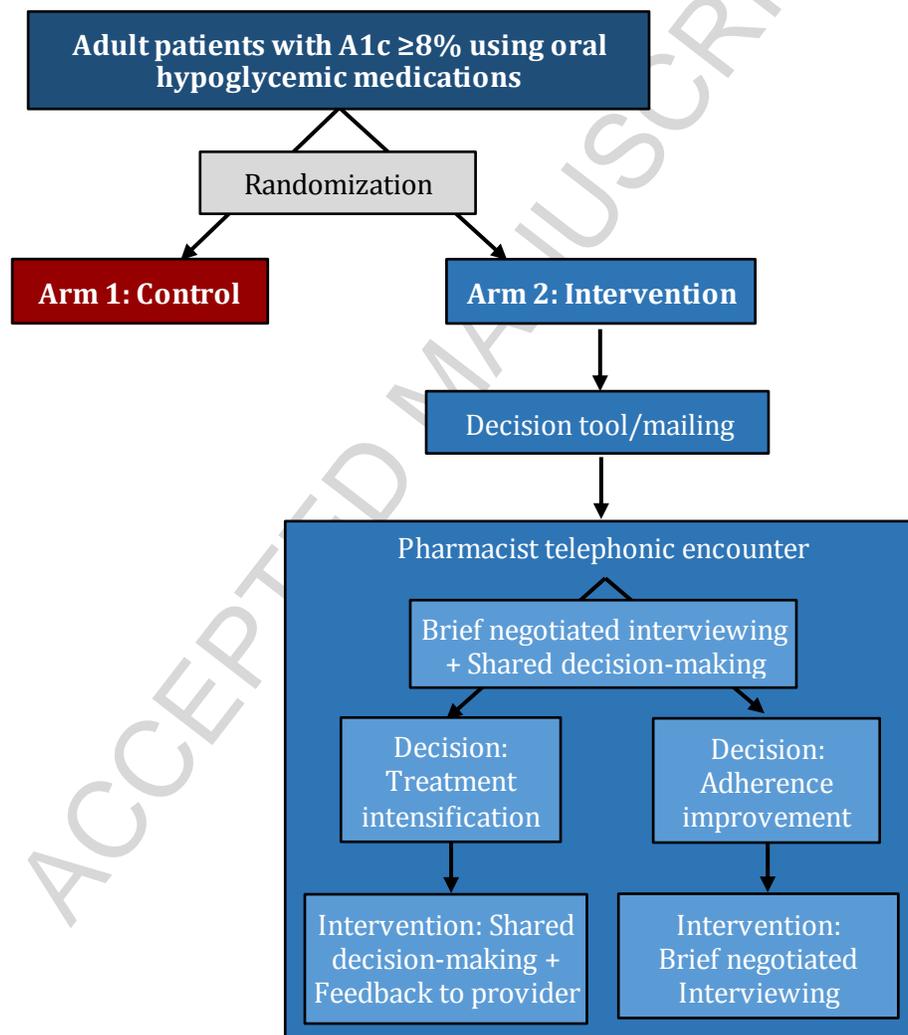
METHODS/DESIGN

Overall study design

ENGAGE-DM (ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus) is a pragmatic, prospective, intention-to-treat, randomized controlled trial designed to examine the impact of a novel intervention among

patients with T2D that combines behavioral interviewing and shared decision-making delivered by pharmacists over the telephone compared with usual care (Figure 1). After the completion of the trial, we will examine whether a patient's response to the intervention could have been predicted based on their demographics, comorbidities or medication treatment-related factors.

Figure 1. Overall trial design



The trial is funded by AstraZeneca, was approved by the institutional review board of Brigham and Women's Hospital and the privacy board of Horizon Blue Cross Blue Shield of New Jersey, and is registered with clinicaltrials.gov (NCT 02910089). The authors are responsible for the design and conduct of this study and all meet International Committee of Medical Journal Editors (ICMJE) criteria. The academic authors will be responsible for performing the study analyses, writing the first draft of the manuscript as well as substantive edits and the submission of its final contents for publication regardless of the study findings.

Study setting and subjects

This trial is being conducted among commercially-insured individuals whose medical and prescription benefits are administered by Horizon Blue Cross Blue Shield of New Jersey (Horizon). Horizon is the largest health insurer in New Jersey and administers plans for over 3.8 million beneficiaries.

Following the principles of pragmatic trial design, potentially eligible patients for inclusion in this study were those who: (1) were ≥ 18 years of age, (2) had filled a prescription for 1 or more oral hypoglycemic agents within the prior 12 months, and (3) had evidence of poor glycemic control ($A1C \geq 8\%$) within the previous 6 months, assessed using the most recent A1C lab values provided to Horizon Blue Cross Blue Shield. If patients had multiple A1C lab values, the latest value was evaluated. An A1C threshold of 8% was chosen based on the minimum threshold that nearly all patients should achieve based on guidelines from the American Diabetes Association (ADA); it is also a threshold for major quality measures for health plans.^{15,16} Patients were excluded if, prior to identification, they

had fewer than 3 months of continuous enrollment in the health plan, had recently filled insulin (e.g., to exclude patients with type 1 diabetes), or had no available telephone contact information, which would preclude contact for enrollment and delivery of the intervention.

Enrollment and randomization for the study began in October 2016. In total, 1,400 subjects have been randomized in a 1:1 ratio to the intervention or control group using a random number generator. The randomization date was defined as the day of data query in which the patients were identified as being eligible for inclusion and assigned to a group in the study.

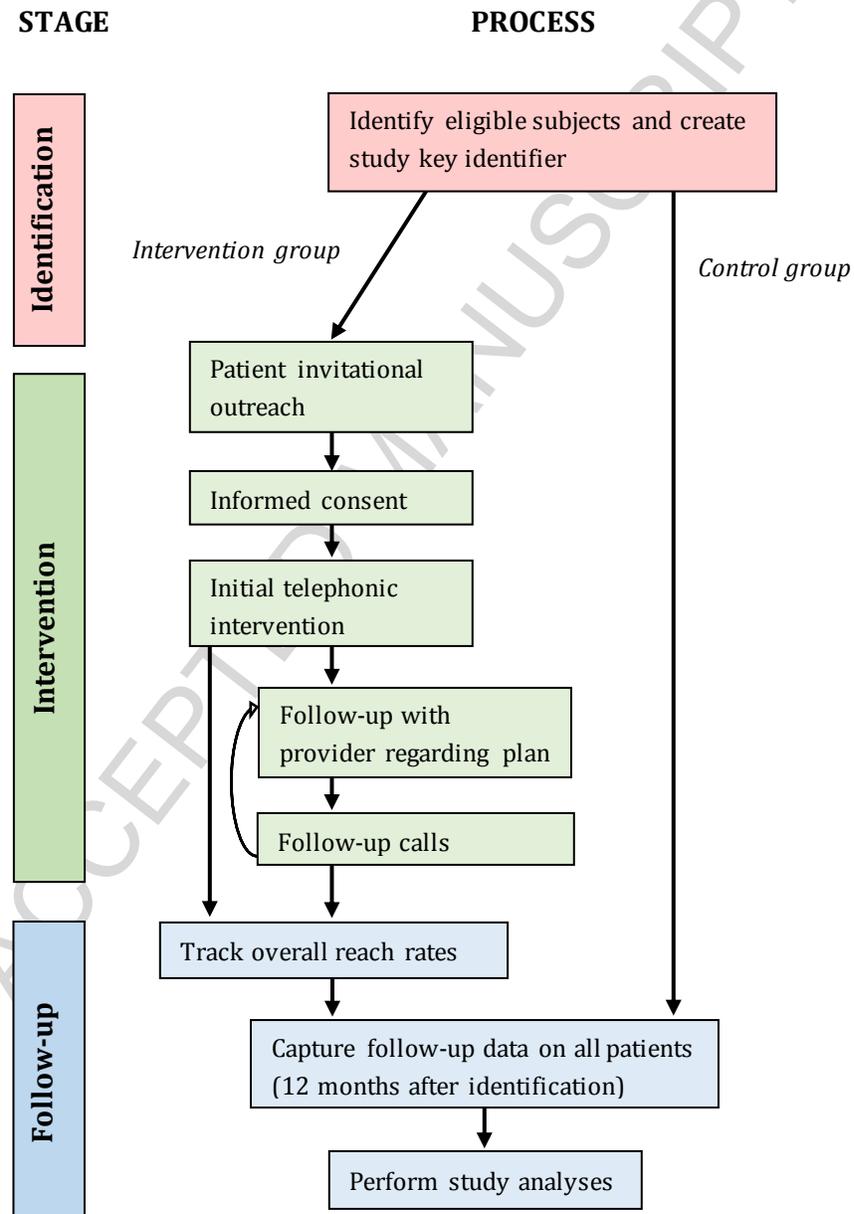
Study Procedures

The overall study procedures are shown in Figure 2. Once identified, patients assigned to the intervention group were sent an invitation letter informing them about the study. The initiation letter included a simple, one compartment per day, pillbox and a shared decision-making tool to prime the patients for telephone encounters with pharmacists (Appendix Figure 1). This tool was developed using the principles of decision aid design and incorporated concepts from other previously-validated decision aids.^{14,17-19} Prior to study launch, the study team solicited direct feedback on the shared decision-making tool and other patient-oriented materials from patients in local diabetes clinics and diabetic support groups. This patient feedback was used to refine both the tool and other materials in accordance with guidelines on conducting shared decision-making.^{17,18}

Within a week of the mailing, patients were contacted by telephone to participate in the intervention or to schedule the future delivery of the telephone intervention and to

obtain recorded verbal consent to participate. At least 3 attempts were made to contact each eligible subject.

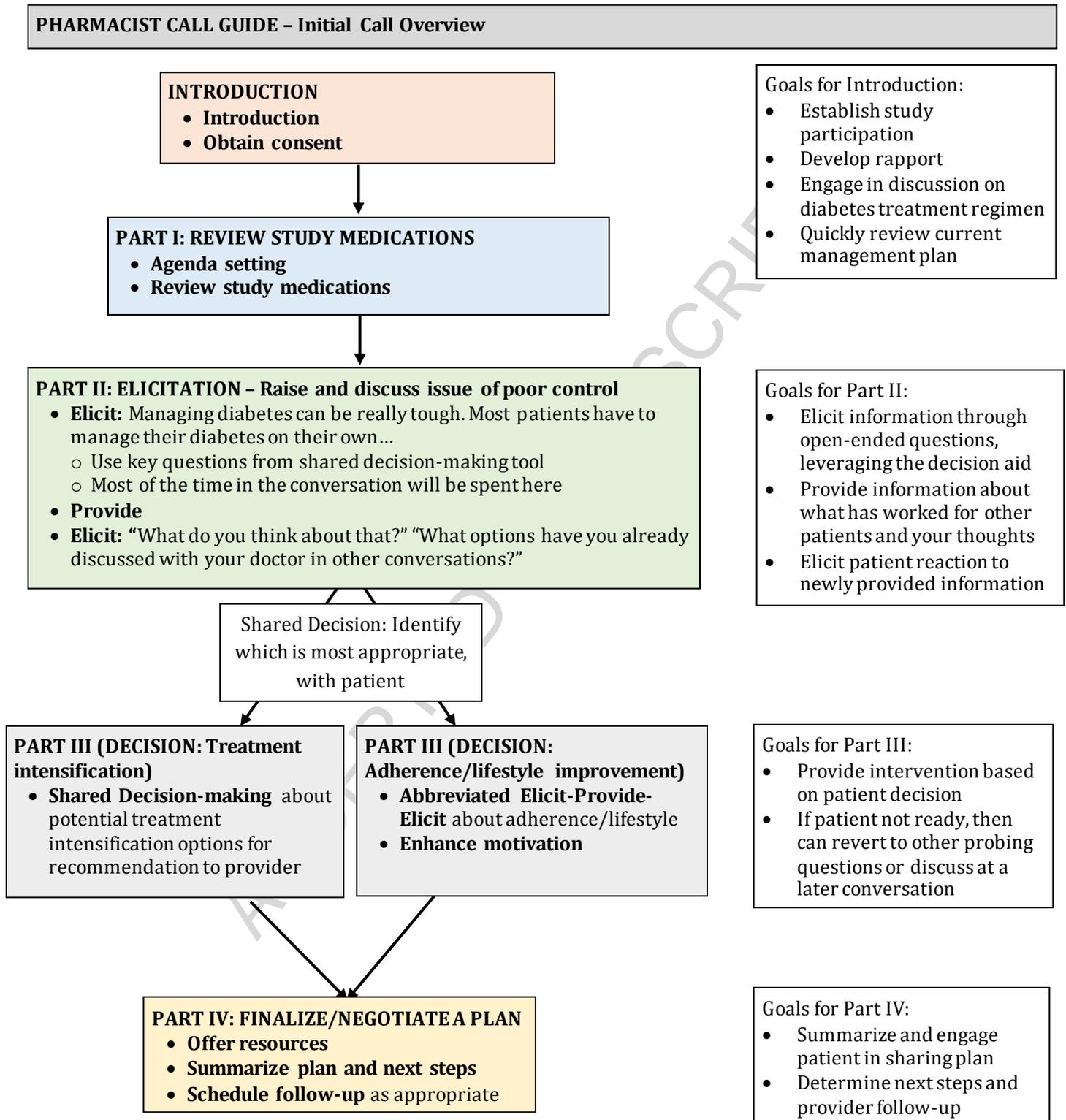
Figure 2. Study procedures



Intervention

The central component of the intervention is a novel behaviorally-tailored telephone intervention (see Figure 3). The initial call is organized based upon the principles and steps of brief negotiated interviewing and guides patients through a process that identifies their motivations and leads to a consensus of decision choices.^{24,25,26} The call begins with a review of study medications, the goals of which are to engage patients and establish rapport, and then proceeds into discussions of issues and barriers to glucose control using open-ended questions to help elicit patient preferences and preferred actions. The mailed shared decision-making tool is also used to help guide this discussion. At the end of this process, the goal is for the pharmacist and patient to reach a shared decision about how to improve the patient's diabetes control. As seen in Figure 3, the means to come to this decision involves shared decision-making principles and the mailed tool.

Figure 3. Overview of semi-structured call guide



For patients who choose treatment intensification, shared decision-making is used to help patients identify the specific treatment option that they would prefer. Shared decision-making is a collaborative process where treatment decisions are made in a two-way exchange of information that integrates both current medical evidence and the patient's needs and preferences to facilitate treatment choices consistent with a patient's own goals.¹²⁻¹⁴ We adapted the Diabetes Medication Choice decision aid¹⁷ for telephone use by having the pharmacists ask patients what characteristic of medication-taking is most important to them (e.g., cost based on formulary prices, side effect profile, ease of use, administration) and guiding them to potential options based on their preferences. The proposed plan for treatment intensification is communicated in writing by the pharmacist to the patient's provider. Ultimately, any therapeutic decision (e.g. to change or intensify treatment) is made by the patient's own treating physician, but the pharmacists will monitor any changes in the plan.

For patients who choose to focus on improved treatment adherence, a second, separate brief negotiated interviewing-based intervention is undertaken to help patients identify their barriers and propose potential solutions. In this intervention, the pharmacists use open-ended questions about patients' medication use and lifestyle habits to elicit barriers to medication adherence, exercise, and healthy diet. This process is used to help the patient brainstorm and identify potential solutions to these barriers with the pharmacist's support and recommendations. These solutions are then tailored to the patients' needs; some of these include pill organization and reminders, use of mail order or longer supply medications, referral to dietitian support, counseling about diabetic meal plans, recommending the use of adherence or exercise apps or alarms, exercise

recommendations, or mailed materials. The proposed plan for adherence or lifestyle improvement is communicated in writing by the pharmacist to the patient's provider.

Follow-up "booster" phone calls by the pharmacists are used at least 3 more times to support the intervention. These follow-up calls repeat some of these themes and continue to engage the patient in discussions surrounding their barriers to disease control.

For this study, the intervention is delivered by trained and licensed pharmacists from Magellan Rx Management, a drug benefit management company that provides pharmacist-delivered telephonic disease management services. Prior to the start of the study, the pharmacists underwent a training program that included script development and role-playing exercises with feedback by the study team. To enhance replicability of the intervention in actual care and in future studies, the pharmacists use semi-structured call guides for both the initial intervention and follow-up 'booster' phone calls, developed by the study team with direct input from patients. An overview of the guide for the initial call is shown in Figure 3.

In addition, the specific components of the intervention that are administered to each patient, including the number and frequency of the phone consultations, are being explicitly tracked to facilitate future reproducibility and scalability. The decisions by the patients, such as whether to intensify treatment or improve adherence or lifestyle control are also being tracked. Data management is primarily performed by Horizon Analytics and secondarily by Brigham and Women's Hospital. Data queries are raised for inconsistent, impossible or missing data. Patients in the control group are not contacted in any way.

Outcomes

The study outcomes and their definitions are shown in Table 1. Follow-up of all subjects will end 12 months after their randomization date or until they lose insurance eligibility. The trial's primary outcome is glycemic control, which will be measured by the pre- to post-intervention change in mean A1C levels in each group using data provided to Horizon as part of quality improvement monitoring. Follow-up will begin from the date of assignment. The A1C result recorded closest to the 12-month end of follow-up will be used for the primary analysis. For subjects with missing outcome data, multiple imputation will be used to impute missing values.²⁰ This approach is used to generate multiple results for missing values based on the underlying distribution of the available data. We will test the robustness of this approach with sensitivity analyses that use alternative methods of handling missing data.

Table 1. Study outcomes

Primary outcome
<ul style="list-style-type: none"> • Pre- to post-intervention change in mean glycosylated hemoglobin) levels
Secondary outcomes
Glycemic control: <ul style="list-style-type: none"> • Proportion of patients achieving optimal A1C control (<8%) in the follow-up period
Medication adherence: <ul style="list-style-type: none"> • Continuous proportion of days covered (PDC) • Proportion of patients achieving optimal adherence (PDC\geq0.80) in the follow-up period

Secondary outcomes of interest include other glycemic and medication adherence outcomes. The secondary glycemic outcome will include the proportion of patients achieving optimal glycemic control. Optimal glycemic control will be defined as the

proportion of patients who achieved an A1C result $<8.0\%$ in the follow-up period. This conservative threshold is based on the minimum threshold that nearly all patients should achieve based on guidelines from the American Diabetes Association (ADA) and quality measures used to assess the performance of health plans.^{15,16}

Medication adherence will be measured using filling patterns in pharmacy claims data for medications that qualified a patient for inclusion in the study.²¹ For each medication, we will create a drug supply diary linking all observed fills after initiation based on dispensing date and days' supply. Different drugs in the same chemically-related therapeutic class (e.g., sulfonylureas) will be considered to be interchangeable. From these supply diaries, we will calculate the proportion of days that patients had medications available to them, or the proportion of days covered (PDC), by dividing the number of days with medication available by the number of days during follow-up.²² If a patient loses continuous eligibility during the year after the index date, the PDC will be calculated based on the number of days available. Using this PDC measure, we will observe the mean PDC in each study arm and the proportion of patients achieving optimal adherence (defined by ≥ 0.80 PDC) as adherence outcomes in the follow-up period. In a sensitivity analysis of this outcome, medication adherence will be measured by calculating the PDC beginning from the first fill of a medication after assignment until the end of the 12-month follow-up.

As secondary analyses, we will also measure healthcare spending and healthcare resource utilization, including outpatient visits, emergency room visits, and hospitalizations, in the follow-up period and compare the two study groups. We will also descriptively examine the number of follow-up calls and the number of patients who

choose each type of decision (e.g., treatment intensification or adherence/lifestyle improvement).

Analytic Plan

We will report the means and frequencies of characteristics prior to assignment separately for patients in the intervention and control groups and compare these values using t-tests, chi-square tests, and their non-parametric analogs, as appropriate. The primary and secondary outcomes will be evaluated using intention-to-treat principles among all assigned patients. Within the intervention group, patients who choose to speak with a pharmacist may differ from those who do not, and an intention-to-treat analysis in this randomized study ensures unbiased comparisons to the control group. In the primary analysis, glycemic control will be compared using generalized estimating equations with an identity link function and normally distributed errors. If there are differences in baseline characteristics between study groups that are believed to be confounders, we will repeat our analyses after adjusting for these covariates in multivariable regression.

In secondary analyses, we will also explore any potential differences in effectiveness by pharmacist delivering the intervention by evaluating effect measure modification and using interaction terms. We will also repeat our analyses with longitudinal modeling methods in generalized estimating equations that incorporate any additional A1c laboratory values in the 12-month follow-up period, for both the primary outcome of change in A1c and secondary outcome of the proportion achieving optimal control. Secondary analyses of healthcare spending and healthcare resource utilization will use a

similar approach as the primary analysis, except that we will use logit link functions with binary errors or log link functions with Poisson errors, as appropriate.

After the study is completed, the second phase of the project will examine whether patient response to the intervention can be predicted based on patient sociodemographic, clinical, and medication use characteristics. In specific, we will develop a series of regression models, incorporating different sets of patient characteristics as predictors and evaluate each model for its ability to predict patients who did and did not meet the glycemic and medication adherence targets during the follow-up period. We will evaluate discrimination, or the ability of the model to distinguish between patients who do and do not experience the outcome using the C-statistic (1.0 indicates perfect prediction and a value of 0.5 indicates no association).^{23,24} Pseudo R-squares will be used to assess model performance by examining the degree of variation explained, ranging from 0 (no variation explained) to 1.0 (all variation explained).²⁵

Sample size considerations

Our study should be sufficiently powered to detect small but clinically meaningful changes in the primary outcome. Assuming that 30% of study subjects in the intervention arm agree to participate in the intervention, we randomized 700 individuals to each of the intervention and control groups in order to achieve 80% power to detect an average change in A1C of 0.5% between the intervention and control groups at an alpha threshold of 0.05 with a A1C standard deviation=1.9, accounting for 25% rate of loss-to-follow-up.^{26,27} With this sample size, we will also have the power to detect at least a 4% absolute

difference in adherence (i.e., mean PDC levels) between the intervention and control groups, assuming baseline rates of 50%.

DISCUSSION

Although medications can effectively reduce high blood glucose levels, poor diabetes control is common, leading to preventable complications such as stroke, heart disease, and kidney failure.¹ Treatment with medications such as oral antidiabetic drugs are the mainstay of therapy for many patients with T2D, but many patients do not achieve the optimal reductions in weight, blood pressure or glycosylated hemoglobin, and might benefit from additional therapy.¹⁶ However, among patients with poorly controlled disease, it is often not clear whether the problem is attributable to the healthcare provider's failure to appropriately intensify therapy, the patient's non-adherence to prescribed medications, the patient's unwillingness to accept new treatments or a combination of these factors.^{3,4} There is growing evidence supporting several different patient engagement techniques, including shared decision making and brief negotiated interviewing, that could be employed in this exceptionally common situation.^{5,6} Even though these techniques are hypothetically complementary, no studies have attempted to combine these two approaches. Consequently, we designed the ENGAGE-DM pragmatic trial to study the impact of these techniques on patients with poorly controlled diabetes.

There are several limitations to this trial that may be encountered. Patients may not have a lab value in the 12-month follow-up period, which may lead to incomplete assessment of clinical outcomes, but we will use commonly used multiple imputation approaches to address this challenge and have factored this into our power calculations.²⁰ The potential for lack of complete clinical data is a common challenge for health insurers.

However, the use of secondary outcomes of medication adherence (i.e., proportion of days covered) will not be affected by the potential lack of missing laboratory information, and higher medication adherence is known to be associated with improved clinical outcomes.^{28,29} For the secondary outcome, patients who fill their prescriptions by paying cash or using low-cost generic programs may not have adjudicated claims reflecting these transactions and thus may be misclassified as being non-adherent.^{31,32} However, we expect any misclassification introduced by this claims inaccuracy to be non-differential between the study arms, and the ability to assess the impact of the intervention on disease control is unaffected by this potential inaccuracy. These findings will also not generalize to patients with other types of diabetes, such as gestational diabetes or prediabetes.

The ENGAGE-DM trial examines a highly-scalable health system and population health intervention that provides a patient-centered approach to chronic diseases management. This novel patient-centered approach integrates two increasingly used methods of engaging patients, brief negotiated interviewing and shared decision-making, delivered in a structured manner. If the intervention is effective, this structured approach is expected to be reproducible in other clinical environments and by other health insurers. Moreover, this study will also provide generalizable information about how to use a pragmatic design that evaluates clinically-relevant outcomes using routinely-collected data. Finally, the use of predictive analytics will also provide policy-relevant information about who is most likely to benefit from these two patient engagement methods in real-world practice.

ACKNOWLEDGEMENTS

We wish to thank several individuals for their assistance with the trial, including the pharmacists and technicians at Magellan Rx Management for patient recruitment, engagement and delivery of the intervention, the analytics team at Horizon Blue Cross Blue Shield for database management, and clinical study managers at AstraZeneca for managerial assistance.

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APPENDIX

Appendix Figure 1. Shared decision-making tool

A. Side 1



How do I manage my diabetes?

Managing diabetes can be really tough. What do I do now to manage my diabetes?

- Take my medicine(s) every day as prescribed.
- Carefully watch my diet.
- Be physically active and/or exercise regularly.
- Test my blood sugar regularly.

What is the hardest part about keeping my blood sugars under control?

- Taking medicine(s) every day as prescribed.
- Following a dietary plan for diabetes.
- Being physically active or exercising.
- Testing my blood sugar regularly (if applicable).

What hemoglobin A1c value is recommended for me?

- <6% <7% <8% I don't know

Hemoglobin A1c measures your average blood sugar for the past three months. High blood sugar resulting from diabetes can damage your eyes and kidneys, and can also put you at risk for heart disease and stroke.

ACC

B. Side 2

What am I willing to do?*Please save this card for when you speak with a clinical pharmacist.***To improve how well I manage my diabetes, what would I be willing to do?**

- Make sure I take my medicine(s) regularly.
- Improve my diet or exercise regimen.
- Take more medicines or insulin.

How much do these strategies lower hemoglobin A1c?

Improve regularity of medicine
use or lifestyle: 0.5-1%

Additional
medicine: 0.5-1%

To speak to a clinical pharmacist about any other questions you have about your diabetes, please call us at: 1-888-XXX-XXXX.

I have scheduled my pharmacist phone appointment for: _____

ACCEPTED