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Pilot randomized controlled trial Protocol: Life context-informed pre-visit planning to improve care plans for primary care patients with multiple chronic conditions including diabetes

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Abstract

Background: Multimorbidity is common, and care is impacted by patient life context. Effective, efficient interventions to improve patient-centered outcomes such as perceived treatment burden are limited. There is a need for interventions that integrate patient contextual information into primary care encounters to improve such outcomes. Patient life context is a multitude of factors that influence a patient's life and healthcare, including social determinants of health and broader elements such as family and work demands.

Methods: This pilot randomized controlled trial (RCT) protocol will compare standard pre-visit planning to *context-informed* pre-visit planning that incorporates the patient's life context, for patients with diabetes plus other chronic comorbid conditions. Primary outcomes include measures of trial protocol and intervention feasibility and acceptability: physician study and visit perceived burden, patient satisfaction, and patient, physician and staff experience with the trial. Additional measurements of intervention impact include: initial estimates of effect size on patient treatment burden and other patient-oriented outcomes, change in glycemic control, and other intermediate medical outcomes.

Discussion: This intervention is novel as it collects patient life context information using a direct person-to-person approach, allows physicians to review the information prior to patient arrival at the clinic and, where appropriate, incorporate it when negotiating treatment plans, and is longitudinal, summarizing evolving contextual information over time. This pilot RCT has the potential to demonstrate trial protocol and intervention feasibility and acceptability, and estimate effect size on patient and provider outcomes, to inform for a future, definitive RCT.
Trial Registration: This trial was registered at ClinicalTrials.gov prior to patient enrollment: NCT04568382

Keywords

Multiple chronic conditions, diabetes, context, patient context, life context, social determinants of health, social needs, pilot RCT

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Introduction

Background and rationale

For the one third of Americans who have multimorbidity (or multiple chronic conditions (MCC), as the more common term in the US)—defined as two or more long-term health

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problems—care remains fragmented, with substantial care burdens, costs, functional limitations, and premature mortality rates.[1,2] Patients, their caregivers, and their primary care providers (PCPs) are faced with a daunting list of care needs for those with MCC, often conflicting with the patient's life context. Patient contextual information is the summary of a multitude of factors that influence a patient's life and healthcare, including social determinants of health (SDH) as well as broader elements such as: family dynamics, job demands, financial resources, cultural or spiritual beliefs, health attitudes and beliefs, and access to healthcare.[3,4] Effective interventions for patients with MCC are limited;[5] research suggests that failure to integrate evolving contextual information into clinical care plans may limit intervention effectiveness, since the care plans may be infeasible or overly burdensome to patients, or fail to meet their most pressing needs and concerns.[4,6,7] There is a need for interventions that integrate patient contextual information into primary care encounters to improve patient-centered outcomes such as perceived treatment burden. However, how best to collect and then incorporate this contextual information in already busy practices is not known. Our objective with this pilot trial is to develop and test a clinic-based intervention to integrate patient life contextual information with physician-patient shared decision-making to optimize care processes and outcomes for persons with MCC.

Past work has demonstrated that a patient's context influences their ability to complete self-care,[8] and physicians often miss contextual information mentioned indirectly during office visits.[9] Patient navigation, one approach to incorporating patient context into chronic disease care, has been shown to improve patient self-care.[10] However, this approach largely bypasses patient-PCP outpatient encounters, the most successful setting for MCC interventions[5] and the setting in which most care plans are formulated and modified over time. To date, interventions that consider patient contextual information in office visits have been limited in the incorporation of contextual information in ways that could hinder their effectiveness in addressing patient-centered outcomes.[11–13] For example, interventions that limit patient-report of life context to pre-defined context areas minimize the breadth of contextual needs addressed and interventions that required patients to use technology (the internet or tablets) to share their concerns create a barrier for some individuals. Interventions that ask the patient to report data via form or portal might invite less sharing and doesn't allow prioritization of concerns the way a direct, interactive person-to-person approach might. Also, requiring patients to share their contextual information during encounters, rather than PCPs receiving it before a visit, adds to visit burden and competing demands on clinician time.

The intervention in this pilot trial is the integration of information about patient life context into pre-visit planning (PVP) as a method to help PCPs develop care plans that better fit the needs of patients with MCC and thereby improve patient-centered outcomes, while avoiding disruption of clinical workflows. In standard PVP, non-PCP health care team members call patients to gather and prioritize key information prior to each office visit, resulting in enhanced patient experience, increased patient engagement, and improved care efficiency,[14] including improved testing adherence in diabetes.[15] To date, standard PVP has focused on biomedical needs, without incorporating information about the patient's life context. PVP as a method to gather information is an ideal method to gather dynamic contextual information as it allows the PCP to quickly review summarized contextual information prior to each office visit, leaving the visit for counseling and decision-making with the patient. Our intervention, context-informed PVP (CI-PVP), is based on a conceptual model of care prioritization for MCC, constructed from our prior qualitative findings, the Chronic Care Model,[16] the Cumulative Complexity Model,[8] and other research asserting that: 1) Contextual information is a key element of health care for MCC;[3] 2) Patients desire good health but high treatment burdens contribute to poor adherence;[8,17,18] 3) PCPs desire more effective and efficient tools to care for patients with MCC;[11,19] 4) Proactive providers prepared for office visits support better health outcomes in chronic disease;[16] 5) standard PVP improves care efficiency and patient engagement;[14,15,20] and 6) Reduced PCP administrative load leads to optimal patient care.[20,21]

We developed the CI-PVP intervention based on our preliminary qualitative data, the prior relevant research literature and discussions with stakeholders to ensure it is welcoming, useful, and fits current workflows. This intervention is novel as it collects and prioritizes contextual information using a direct person-to-person (nurse to patient or patient caregiver) approach;[11,12] allows PCPs to review the information prior to patient arrival at the clinic and, where appropriate, incorporate it when developing treatment plans; and is longitudinal, summarizing dynamic contextual information over time.[11,12,22] During this pilot randomized controlled trial (RCT), we will compare the CI-PVP that includes both patient life context information and biomedical needs to standard PVP that includes only biomedical needs to determine intervention feasibility and acceptability, gather information to help guide future dissemination and implementation, and provide an initial estimate of effect size on patient and provider outcomes to inform power calculations for a future, definitive RCT.[23,24]

Objectives

Our objectives for this pilot RCT are:

- To demonstrate feasibility and acceptability of the intervention and trial protocols

o *Hypothesis 1:* Patients will appreciate their life context and social determinants of health being discussed and/or incorporated into their healthcare

o *Hypothesis 2:* Health care professionals (MA, LVN, physician) will not perceive an increased burden for collecting, reviewing or using this information.

- To quantify the impact of the intervention on the burden of diabetes and other chronic condition care for patients

o *Hypothesis:* Treatment burden will be highest for patients with poor disease control and/or higher life context and social determinants of health needs, and discussion of life context information with the healthcare team will lower patient-perceived diabetes treatment burden

Trial design

We propose a two arm, pilot cluster randomized controlled trial designed to be double blinded to examine feasibility and acceptability, and to produce an initial estimate of effect size on patient treatment burden, of a new context-informed PVP approach (CI-PVP) compared to standard PVP for patients with diabetes and other health conditions, also described as multiple chronic conditions including diabetes.[18,19] We will use 1:1 allocation ratio, with patients clustered under physicians, and randomized to the intervention or control at the level of the physician.

Methods: Participants, interventions, and outcomes

Study setting

Clinical Setting. An academic family medicine clinic on the west coast of the U.S. will serve as the trial site, with family medicine resident, faculty, and staff physicians. The area served is one of the most socio-demographically diverse areas of the country,[25] includes rural, urban, and surburban areas, and the clinic accepts patients with commercial insurance, Medicaid (straight Medicaid and Medicaid geographic managed care) and Medicare (both Fee For Service and Medicare Advantage).

Eligibility criteria

Both family medicine primary care physicians (PCP) and their patients will be recruited for this study.

The target patient population is patients with multiple chronic conditions including diabetes. This was chosen as the goal is to develop an intervention to serve those with multiple chronic conditions and using diabetes mellitus (type 1 or type 2, excluding gestational) as a unifying condition allows for the use of a validated instrument to measure treatment burden in diabetes and both a patient registry and standard PVP process for diabetes that are already in place in the clinic to support recruitment and intervention implementation within normal clinic workflows. Diabetes also has high time and energy burden. Patients with diabetes have shown improved completion of recommended diabetes-related blood tests and attendance at appointments after standard PVP,[15] so patients with MCC that includes diabetes are likely to respond to CI-PVP where collecting contextual information in addition to reminding patients to complete recommended tests has the potential to enhance person-centered care.[3,5,15,26] Patients are eligible if they are: adults, have diabetes per the Healthy Planet 2020 criteria registry through the EMR, self-identify as having at least one of the below additional chronic conditions to be considered to have multiple chronic conditions, have a visit coming up with one of the enrolled PCPs, speak English well enough to complete the surveys in English (written or verbally) and are willing and able to consent. Eligible patient chronic conditions, chosen for their higher prevalence and clinical impact: hypertension, dyslipidemia, obesity, chronic heart failure, coronary artery disease/other cardiovascular disease, chronic kidney disease, asthma, chronic obstructive pulmonary disease (COPD), depression and/or anxiety, arthritis (any type), chronic back pain, osteoporosis.[27–30]

For physician participants, family medicine residents in their 2nd year and 3rd year of training and staff family physicians with continuity practices at the trial clinic site are eligible. Physicians involved in the development of the trial (i.e., trial authors, medical director who approved study processes) are ineligible.

Who will take informed consent?

Patients will be recruited off the clinic schedule up to 2 weeks prior to their scheduled appointment and until the day before their appointment. Written informed consent will be obtained from the patients by the research assistant at the time of recruitment. Informed consent for the trial will be done in parallel with the CI-PVP process so that the CI-PVP call may follow or precede the study recruitment call to not slow clinic operations as approved by clinic management and the research ethics review board. Informed consent will be obtained from the PCPs by the study PI who is a faculty family medicine physician at the clinic via email at the time of recruitment, as the PCPs' involvement is limited to surveys and normal clinical care.

Additional consent provisions for collection and use of participant data

Patients will sign a HIPAA consent for access to their electronic medical records (EMR).

Interventions

Explanation for the choice of comparators

The two comparators in this trial are standard PVP (standard current clinical practice) and CI-PVP. The PVP process was chosen as the target of the intervention as it is a clinical practice innovation to make office visits more efficient and effective by gathering information prior to the office visit, leaving more time in the office visit for counseling and decision-making with the patient.[14] Standard PVP at the trial clinical site, as in other offices that use it nationally, focuses on biomedical issues and simple clinical care process tasks, such as collecting test results and placing pre-visit lab orders. For this study, the intervention CI-PVP adds the collection of patient context information to the standard PVP workflow and documentation.

Our hypothesis is that care plans developed in consideration of the patient's contextual issues and priorities, and harnessing the power of the patient-PCP relationship during the office visit discussion of the patient's context and treatment needs, will lead to more patient-centered care plans, lower patient-perceived treatment burdens, improved adherence to the care plan (self-care, office visits, and tests), and better clinical outcomes. Patient-perceived treatment burdens are expected to be lower due to: actual reductions in treatment demands; improved patient workload capacity through problem-solving treatment plan elements into their schedules or improving self-efficacy and/or knowledge such that the treatment plan now feels less burdensome to the patient; and/or decreased sense of burden from therapeutic discussion of their whole-person needs with their PCP.[8] As interventions for MCC are most effective when they target specific patient needs and outcomes, especially functional outcomes,[5] we expect our proposed intervention—which will target patient-identified context needs with a goal of reducing treatment burden—to be successful.

We developed the below conceptual model (Figure 1) on the potential role of CI-PVP, based on the Chronic Care Model,[16] Cumulative Complexity Model (Minimally Disruptive Medicine)[8] and our preliminary work.[19]

Intervention description

Standard pre-visit planning (control)

Our health system currently uses a licensed vocational nurse (LVN) to conduct standard PVP in the 2 weeks prior to every office visit for selected patients. A report is run on the upcoming schedules to identify patients meeting Healthy Planet 2020 criteria for the diabetes registry. The nurses then review the patients' charts to look for diabetes care gaps such as no hemoglobin A1c in the last 6 months or no diabetic foot exam in the last year, reach out to patients to complete outstanding labs or other tests, and note these in a standard PVP note in the list of patient encounters in the EMR (in the same manner clinic visit notes and telephone calls are listed). PCPs are able to review standard PVP information in the standard PVP note, and past standard PVP notes, prior to the patient's arrival in the office.

Context-informed pre-visit planning (intervention)

Our intervention will modify the standard PVP to add a brief question designed to collect and prioritize patient contextual information currently impacting their health while working within current workflows and with existing technology. During CI-PVP, the nurse will ask a question to elicit patient contextual information after introducing the concept of needing more information to best take care of them: "Is there anything going on in your life that is impacting your health or ability to follow your doctor's recommendations that you would like your doctor to know about?" This question was developed from the literature on contextual information,[3,9,27] and our preliminary qualitative work on

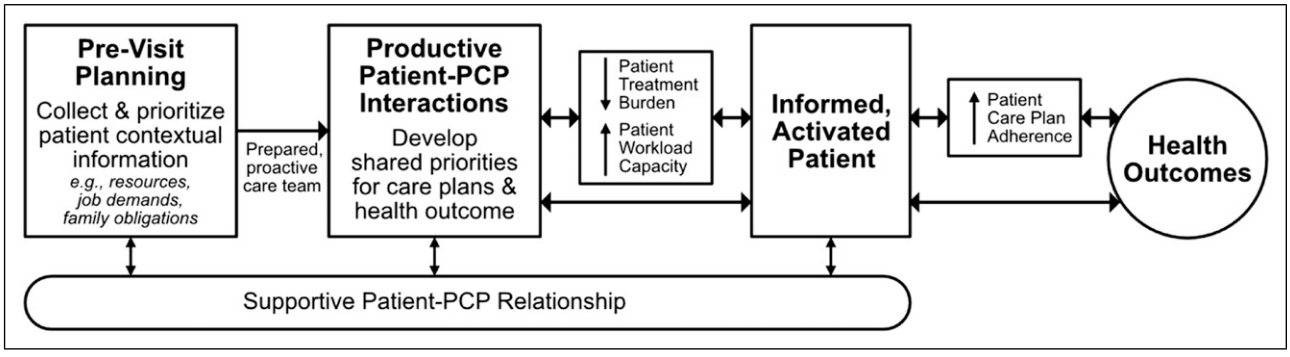

Figure 1. Conceptual Model of the potential role of CI-PVP in patient health. Patient contextual information summarized before the office visit supports PCPs to be prepared for patient needs, leading to productive interactions, supported by the patient-PCP relationship. PCPs and patients set shared priorities and develop a context-informed care plan. This leads to an activated patient who is able to adhere to the care plan in their life context, improving health outcomes.

understanding how PCPs and patients prioritize care in MCC,[19] and is open-ended to elicit broad information without avoid restricting responses as has occurred in previous PVP-type interventions[11,12] while allowing a "no issues" response for patient comfort and to avoid eliciting low impact life context. The nurse will then listen to the patient's answer, asking clarifying or probing questions as needed. If multiple concerns are present, the nurse will guide the patient to prioritize them. The nurse will then record a brief (few words to one sentence) summary of the patient's responses in the CI-PVP note (a standard PVP note that includes CI-PVP information). This summary is kept short to reduce the nurse's work time and for ease of PCP review. The study design allows for multiple patient visits during the trial period. If a patient has subsequent visits, since contextual information is dynamic, in follow-up CI-PVP, nurses will ask patients about their current issues and what has changed, referring to previous CI-PVP notes. The nurse will be trained by the PI to conduct CI-PVP, a family physician, and occasional spot-checks will be performed.

Resources

All patients and PCPs have access to clinical social worker referrals as needed for health system and community resources. The nurses conducting the standard PVP calls are knowledgeable about health system processes to access community services and other resources if needed. The nurse conducting the CI-PVP calls will also have a Resource Sheet developed for the study listing health system, community services and other resources that address common barriers to care (care management, lower cost medications, transportation options, etc.) in case it is felt that immediate patient support is needed. The project PI, a physician, is available for contact at all times for immediate patient care needs as well.

Criteria for discontinuing or modifying allocated interventions

The CI-PVP process will be modified if issues arise in the process as requested by the CI-PVP or research staff during the pilot study, and as approved by the IRB.

Strategies to improve adherence to interventions

In most cases, patient participation will be limited to a single study visit and 3 sets of surveys: baseline (pre-visit), after visit (within 2 weeks), and post-study (4 months after the initial office visit.) Adherence to intervention protocol is limited to completion of the survey. Patients will be emailed and called to remind them to complete the surveys and provide support answering surveys if needed (such as doing the survey by phone if they are unable to complete on the computer). Providers will also be reminded by email or EMR staff message to complete their surveys. Providers are encouraged at the beginning of the study and as part of normal practice to review any PVP notes prior to each office visit.

Relevant concomitant care during the trial and post-trial

All standard care is permitted during and after the trial with no changed recommended, required or prohibited by the trial.

Outcomes

For this pilot intervention trial, we will assess the trial protocol and intervention for feasibility and accessibility and measure patient outcomes after the intervention as well as prepare for future dissemination and implementation using mixed methods and the RE-AIM framework.[31] Surveyed outcome measures were chosen that would comprehensively assess pertinent patient outcomes but be short enough in written or telephonic survey format to limit study burden. Patient surveys will collect data at baseline, 2 weeks after the office visit, and at 4 months post office visit. Qualitative outcomes will be assessed by interview. EMR data will be collected by study personnel from the patients' charts.

As this is a pilot trial, we will assess *feasibility and acceptability* of the intervention, trial protocol and outcomes data collection at the patient, nurse and PCP levels. Patient satisfaction with care will be measured at baseline and post-intervention for all patients using the Healthcare Climate Questionnaire.[32] A subset of patients in the intervention arm will participate in a brief semi-structured post-study interview on their experiences with the trial and CI-PVP. The PCPs (both study arms) will be assessed for their perception of the hassle and the helpfulness of participating in the study, using a modification of a 12-item survey developed by our team for a recent study on a primary care intervention for chronic condition management.[33] The CI-PVP nurse and 5 of the PCPs in the intervention arm will also complete a brief semi-structured interview (10 minutes) on their experiences with the trial and any PVP (either standard PVP or the intervention CI-PVP), as well as their observations on patient reaction to the CI-PVP and discussion of life context during the office visit. All PCPs also will be surveyed for visit difficulty[34] after a single MCC visit prior to the intervention period, 1 and 3 months into the intervention period, and post-intervention period, to ensure CI-PVP does not add to visit burden

compared to standard PVP. Patients and providers will be asked if life context of SDH information was discussed during the office visit. This can be compared to SDH and life context noted in the chart. Additional patient and PCP outcomes, detailed below, and discussions among research team members regarding implementation of the intervention will also be used to assess feasibility and acceptability.

We will collect the following the elements of the *RE-AIM Framework*:[31]

Reach: number of patients assigned to the clinic, number of patients on the clinic's diabetes registry, total number of patients seen during the study period, number of patients on the clinic's diabetes registry with appointments scheduled during the study period, number of these patients unable to be reached by phone, number who we contact declined to participate and reasons, and the number who consent but them do not make their appointment.

Effectiveness: We will assess barriers and facilitators to life context information use and implementation of the intervention, attitude toward the intervention, unintended consequences, and recommendations for intervention and implementation modifications using the interviews, surveys, and data from the EMR as detailed below.

Adoption: The Reach and Effectiveness data will inform a summary of key features of the intervention and its implementation, characteristics of the practice setting and patient population that served as facilitators and barriers, and attrition from participation experienced.

Implementation: At the beginning of the study period, stakeholder engagement with nurses and clinical leadership was used to finalize intervention design to fit into the workflow of the practice. During the study, fidelity checks of CI-PVP phone call approach and troubleshooting will provide data on implementation success. The end of study interviews will assess deviations from protocol and their reasons.

Maintenance: We will ask study participants to identify aspects of the intervention they liked best and least, and those they would recommend modifying. We will report on recommended modifications to the intervention protocol for future trials and implementation in other practices.

The outcome measure for *initial estimates of intervention effect is patient treatment burden*, a patient-centered construct that can serve as a measure of patient function.[18] Treatment burden depends on contextual information, and high treatment burden contributes to reduced adherence, care satisfaction, and patient-reported quality of life.[27, 35] Patient-perceived treatment burden can be felt from any combination of comorbid conditions and their treatments in conjunction with patient life context as it includes items such as being able to remember to take medications or annoyance with completing testing. We will employ the Treatment Burden Questionnaire (TBQ), a 15-item measure developed and validated in an MCC population, to assess multiple domains of treatment burden.[27] As the TBQ does not include financial burden questions, we will use the 5-item financial treatment burden subscale from the longer Patient Experience with Treatment and Self-Management (PETS) measure.[35] We will estimate effect sizes for this primary outcome as baseline (pre-intervention) adjusted between-arm differences in mean follow-up scores

As part of this pilot trial, *additional outcomes* will be measured to demonstrate our ability to use the measurement instruments and conduct the chart reviews that will be required for carrying out a larger, multicenter trial of the CI-PVP intervention. These patient measures represent patient subjective and objective health status and health behaviors, as in the long term we expect CI-PVP to improve patient health behaviors and outcomes. We will use validated instruments to assess change from baseline to post-study: patient illness perception (self-view of MCC-related health; MULTIPLeS);[36] self-rated health (Medical Outcomes Study SF-12 instrument);[37,38] level of patient activation (Patient Activation Measure (PAM) short form)[39] and self-care self-efficacy (Perceived Medical Condition Self-Management Scale).[40] We will also collect basic patient demographic data (age, race/ethnicity, sex, marital status, household income, education) and health professional data (years in practice, specialty, sex, race). Additional data abstracted from patient charts at baseline and/or post-intervention will include: chronic conditions, chronic condition medication classes, insurance, number of office visits during the study period, and intermediate measures of health (body mass index, blood pressure, glycosylated hemoglobin, depression, and anxiety symptoms with PHQ-2 or 9 and GAD-2 or 7, as available), appropriate preventative care completed (i.e., flu shot), CI-PVP context and social determinants of health categories recorded in the social determinants of health section of the chart. Regarding PCPs, we hypothesize that the CI-PVP may decrease or not worsen their perceived clinic workload. Thus, we will measure PCP job satisfaction with the validated Physician Job Satisfaction Scale;[41] and burnout with the Maslach Burnout Inventory Human Services Survey for Medical Personnel[42] at baseline compared to 4 months post-study start. Basic demographic data (age, race/ethnicity, gender identity, education, year in training if applicable, years since completing professional education, year in role) will be collected at the start of the study for PCPs.

Participant timeline

Patients will be recruited up to 2 weeks prior to a scheduled office visit. Between study enrollment and the first office visit, the baseline survey will be conducted and CI-PVP completed for the intervention arm. A post-visit survey will be completed at 1–2 weeks after the office visit. At 4 months after the office visit, the end of study surveys will be

completed and then the end of study interview. Patient participants are in the study until end of study survey and interview conducted at 4 months after the initial study office visit. Each patient is planned to have one office visit during the study; however, additional office visits are allowed (and their presence will be captured in the EMR data and accounted for in adjusted analyses). EMR data collection will occur during the study to collect baseline and 4 months post-visit data.

PCPs will be recruited prior to patients and will complete baseline (pre-intervention) surveys at the start of the study. They will complete brief after-visit surveys after each study office visit. After 4 months in the study, PCPs will complete end of study surveys. After the last patient office visit for the study, they will complete an end of study interview.

Sample size

The primary purpose of this pilot study is to assess feasibility and acceptability of the intervention and protocol. We also wish to gain initial estimates of intervention effects on patient treatment burden, our primary outcome, to inform: (1) go/no-go decision-making about whether to pursue intervention development and (2) the design of the future study. To satisfy these requirements, we determined that we would need 95% CIs to be estimated with sufficient precision that for outcomes at a single follow-up time the effect size estimates are less than 0.50 standard deviations wide and that the study provides 80% power to detect true standardized effects of 0.66 with two-sided alpha = 5%.

Using conservative assumptions, one visit per patient, 15 patients per PCP, 6 PCPs (3 PCPs per group), 10% attrition at the follow-up visit, residual within-clinic intracluster correlations of 5%,[43] and assuming only 60% within-patient correlations for repeatedly measured outcomes, we verified that our proposed study design would translate into effective sample sizes of 37 patients per group for patient-level outcomes at a single follow-up timepoint, sufficient to meet our requirements.[43–45] For effect sizes based on pooling follow-up measurements, the effective sample sizes are 61 patients per group for patient-level outcome. Notably, test-retest reliability was 0.76 (95% CI: 0.67 to 0.83) for 2–4 -week measurements of the primary outcome[27] and both the TBQ and PETS scale have reported Cronbach alphas of approximately 0.90 in earlier samples.[27,35]

Recruitment

PCPs will be recruited by direct communication from the PI (primary investigator) to eligible PCPs at the clinic. Once PCPs are recruited, patient recruitment will begin.

Patients will be recruited by direct phone call by an experienced trial recruitment research assistant off a list of potential eligible patients provided by the trial clinic site. Please see Eligibility criteria for more information.

Assignment of interventions

Study physicians will be allocated to intervention or study arm using computer-generated randomization with every other physician assigned to intervention then control with 3 into the intervention arm and 3 into the control arm (1:1 allocation) by the team statistician. The allocations will be communicated by the statistician directly to the nurse conducting the CI-PVP only for purposes of conducting CI-PVP for the intervention group only.

The remainder of the study team will remain blinded to the allocation. REDCap for data management will facilitate blinding of the study team to physician name, patient name, and study arm. EMR data collection will not include any PVP note data collection until after the trial is completed and at that point will be done by a single team member. While the statistician will know the physician assignments from the allocation, he will not know which patients were assigned to each physician and all analyses will be done by study ID, not physician or patient name, and blinded to allocation. Unblinding will occur inadvertently if there is an issue with study protocol or potential patient harm where the PI must access the chart or talk to the nurse conducting CI-PVP and it is evident the patient received CI-PVP.

Participants will be blinded; however, they might be able to surmise their assigned group. Physicians will be blinded to their assigned group but will be able to see patient PVP notes (standard PVP or CI-PVP) and might recognize if the PVP notes are similar to past standard PVP notes (control group) or if they have context information, a change from prior PVP notes (intervention group, CI-PVP). Patients will be blinded to their physicians' assignment. During the consent process, they will be told that they might receive an additional phone call regarding their care, depending on their physicians' study assignment, and so patients experiencing this call might surmise they are in the intervention group. However, patients are called frequently by the clinic and specialty clinics for multiple reasons (confirm appointments, set up appointments, update insurance, check on symptoms, etc) and so they might not identify an additional call or these questions as being part of the study. All patients in the study will also experience a call or text from the clinic to confirm their appointment.

The nurse conducting the CI-PVP and standard PVP will have a list of patients who will receive the CI-PVP call and the nurse will be careful to only ask CI-PVP questions for these patients. As the CI-PVP questions represent a new process and will only be done for a discrete group of patients, contamination by accidentally doing a CI-PVP call to a control patient will be unlikely. We will be able to tell if

this occurred during results analysis by the presence of CI-PVP information in a control chart.

Data collection and management

Plans for assessment and collection of outcomes and data management

Survey data will be collected using REDCap emailed surveys that directly enter data into the REDCap study database. The validated instruments described in the Outcomes section will be used. Interviews will be conducted by an experienced RA and transcriptions and audio reviewed by the qualitative researcher co-investigator. Chart data will be abstracted by the PI, a physician, with secondary data abstraction for quantitative chart data by an RA into REDCap.

Plans to promote participant retention and complete follow-up

The study is 4 months for each patient with 3 collection events needed from the participants: baseline, intra-study after visit (2 weeks after the baseline visit) and end of study at 4 months post-baseline visit. To increase retention and complete follow-up, survey completion will be tracked on an ongoing basis in REDCap. Patients will be called up to 5 times at different times of day on different days to complete surveys and offered to complete surveys over the phone with the RA. PCPs will be contacted by email and through the EMR to complete surveys and asked in-person as needed. Patients will be asked to complete end of study surveys and the end of study interview even if they miss the after-visit survey. EMR data will be collected from all participants including those lost to follow-up. Missing data will be managed as previously discussed.

Confidentiality

Patients will provide written consent to participate in the trial as well as a signed HIPAA consent to allow access to their medical records. All patient identifiers will be served in secure electronic format with access restricted to study personnel and password protected. Study data is managed in REDCap, as above. All participants are assigned study IDs to be used throughout the study; their names and other identifying information is kept on a single page in the REDCap database and only used from recruitment, EMR chart abstraction and compensation. PCP participants will consent by email and will also be assigned study IDs as described for patient participants. For interviews, transcriptions will be de-identified and audio files saved on a secure server with restricted access to the folder and under password protection. All study personnel are trained in ethical conduct of research and patient medical records privacy protections (US CITI and HIPAA training) and will follow all research ethics institutional review board (IRB) protocols.

Statistical methods

A sequential transformative mixed methods research design with equal priority given to the qualitative and quantitative aims of the pilot RCT will be employed. This design was chosen as it allows for multiple approaches and flexibility to both data collection and analysis while using an existing theoretical perspective to guide the study.[46] Consistent with sequential transformative design, this study will incorporate qualitative methods (interviews with PCPs, nurse and patients) and quantitative study outcome measures (surveys, EMR data) to evaluate study outcomes.

Analysis of qualitative data from brief semi-structured interviews to assess trial acceptability and feasibility will be done using content analysis by the team's qualitative researcher and the PI. This qualitative method is appropriate because existing conceptual models will be used to guide data analysis.[47] The team will develop the codebooks based on predetermined codes resulting from the existing conceptual models for chronic condition care and standard PVP described above as well as the RE-AIM framework. Predetermined codes will include implementation, barriers, facilitators, adoption, effectiveness, maintenance, cost, etc. Codes will then be collapsed into categories and subcategories. Once the final codes are defined and agreed upon, the qualitative researcher and a trained research assistant will code independently adding emerging codes to the existing codebook. After coding 1–3 transcripts researchers will meet to discuss and resolve discrepancies before coding the remaining transcripts. Once all transcripts are coded, researchers will meet regularly to discuss the data in relation to the existing theoretical models. At the end of the analysis, we will develop a detailed description of strategies and tools for collecting contextual information as part of PVP and best practices for integrating such information during primary care office visits.

Analysis of quantitative data for patient treatment burden using the TBQ scale[27] and other quantitative outcomes will be conducted by the statistician with assistance of the research team. Primary analyses will be conducted using an intention-to-treat approach to estimate adjusted between-group effect sizes, with both 95% and 75% confidence intervals (CI) reported to inform go/no-go decision-making for a future trial.[48] Additional as-treated analyses will be done on a subgroup as described above. Patients will be analyzed as a single group in each study arm, not by co-morbidity cluster. To accommodate the continuous and binary outcomes, the unbalanced longitudinal data, and the clustered randomized design, we will use generalized linear

mixed-effects regression models (GLMM).[49–51] In each analysis, all available patient-level follow-up measurements (the units of analysis) will be used. For all outcomes except LVN- and PCP-reported study hassle, baseline measures are available and will be included as a covariate, to improve precision. The multilevel structure of the longitudinal patient-level and PCP-level data will be accounted for using random intercepts for each level of nesting (by patients and/or PCPs).[49,52] Sex as a biological variable will be considered by exploring heterogeneity of treatment effects, using interaction terms for sex and treatment group indicators. In exploratory analysis, we will also assess heterogeneity of treatment effects for age, level of comorbidity and race. In addition, we will estimate "dose-response" effects using patient-varying measures of exposure to CI-PVP / standard PVP (number of office visits).

Interim analyses and methods for additional analyses (e.g., subgroup analyses)

Interim analysis is not planned for this pilot trial. Both intention-to-treat and subgroup as-treated analyses will be performed to account for participants not completing offices visits or not receiving assigned CI-PVP.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

In the event of missing end of study survey data, data will be explored for missing not at random data. Sensitivity analyses will be performed using no change and worst-case scenario change (worsened scores to match the worse recorded score change) to replace missing data. For protocol non-adherence, patients not receiving assigned CI-PVP, both intention-to-treat and as-treated analyses will be done.

Plans to give access to the full protocol, participant level-data, and statistical code

Modifications to the protocol and recommendations for future protocols will be submitted for publication. Data access will be granted in alignment with IRB protocols.

Oversight and monitoring

The study will be run by the PI, a primary care physician and researcher, with two trained research assistants and the qualitative researcher co-investigator who will meet 1–2 two times weekly. The trialist co-investigator will be available for meetings on demand as will the study statistician. The clinic will provide the list of potentially eligible patients and a nurse to assist with CI-PVP. A primary care physician-researcher who is not part of the study and is not funded by the supporting grant, will be assigned as a data monitor and will report to the IRB and inform the study PI of issues if they arise.

Adverse event reporting and harms

Adverse events, harms or breaches in trial conduct will be reported to the IRB and data monitor per institution standards. Clinic-related issues will be reported to the clinic medical director.

Adverse events are likely to be few. However, it is possible that there will be unintended consequences of collecting life context information for the patient, nurses or physicians. To mitigate potential emotional or structural risks of sharing life context that needs to be addressed more quickly than waiting for the patient's office visit, such as housing instability or suicidality, a community resources referral sheet and contact number (211) is provided to the nurses conducting the CI-PVP. The PI, a physician, will be available at all times for consult throughout the study as will other physicians working in the clinic that day, and the clinic also has social work referrals available. We note that a study on patient social needs assessment showed that 97% of patients with social needs did not desire these needs to be fixed by the clinical team.[53]

Additionally, we do not expect CI-PVP will remove life context from the patient-physician relationship or damage the patient-physician relationship. The key value of the intervention is to bring more life context into the PCP visit and integrate it into the patient's medical care. PVP "enables the clinician to focus on patient concerns and visit agenda."[13] Our goal is for the PCP to work to the top of their license to delve deeper into life context issues that the patient has identified as affecting their health. A recent study on screening for social needs in primary care showed that 52% of physicians felt they knew their patients better, care was changed in 22.5% of cases, and the authors concluded that assessing patient social needs may improve the patient-physician relationship.[53]

Frequency and plans for auditing trial conduct

Trial data will be immediately collected into REDCap and may be audited anytime by the data monitor, IRB or co-investigators.

Plans for communicating important protocol amendments to relevant parties

Any important protocol modifications will be reported to the IRB and co-investigators prior to implementation and to the clinical trial registry once approved.

Dissemination plans

The results of the pilot trial as well as any modifications to the protocol will be submitted for publication in a relevant journal or for presentation at a scientific conference.

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Authors' contributions

Dr. Magnan is the PI on this study; she conceived the study, led the proposal and protocol development, and summarized the trial protocol for publication. Drs. Jerant, Tancredi and Gosdin contributed to the development of the protocol and to editing this manuscript. All authors read and approved the final manuscript.

Declaration of conflicting interests

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Availability of data and material

All co-authors have access to the final study data.

Ethics approval and consent to participate

The study was approved by the UC Davis Institutional Review Board, Study ID 1619593-1. Written, informed consent to participate will be obtained from all participants as described in the protocol.

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Appendix

Notation

CI-PVP	Context-Informed Pre-Visit Planning
DM	Diabetes Mellitus
MCC	Multiple Chronic Conditions
PCP	Primary Care Provider
EMR	Electronic Medical Record
SDH	Social Determinants of Health (or Social Drivers of Health) RA research assistant IRB instituional review board