Study Protocol and Statistical Analysis Plan

Official title:	Impact of an Interprofessional Shared Decision-making and Goal-setting Decision Aid for Patients With Diabetes
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Study protocol:

Study design:

A two-step clustered RCT will be conducted. The *initial aim* of this project is to assess intervention fidelity and the feasibility of conducting a larger clustered RCT. Due to the complexity of interprofessional team dynamics; we will focus on intervention fidelity at the individual level. The *secondary aim* is to evaluate the impact of the intervention on decisional conflict, diabetes distress, chronic care delivery and health-related quality of life. The use of a clustered RCT prevents contamination of the control group in trials of population-level interventions and thus avoids biased estimates of effect size[1]. The first step will be a provider-directed phase (the intervention will be delivered to the provider only); the second step (which will occur 6-9 months later) will be a provider- and patient-directed phase (the intervention will also be delivered to the patient). The use of the 2-step approach will allow us to monitor barriers influencing uptake by population (provider or patient). We selected a 6-9-month interval for each phase to ensure sufficient time period for health care providers and patients to follow-up with each other, to enable adequate exposure and use of the decision aid.

Participants:

Family practice groups will be recruited from the 14 LHINs in Ontario. Groups that do not have a nurse, dietician or pharmacist on staff, or do not have an electronic medical record capable of identifying patients with diabetes will be excluded. We have the expertise of OntarioMD to develop system-specific algorithms to identify patients with diabetes (Letter of Collaboration). We have the support of the Primary Care Lead for Toronto Central LHIN and a representative Medical Director of a family practice unit (Letters of Collaboration).The research team will contact medical directors of eligible practices to explain the project. Groups for whom not all health care providers have consented will be excluded. Patients with diabetes and 2 other comorbidities will be identified from each consenting practice by the research coordinator through the electronic medical record; those who do not speak English, have documented cognitive deficits, are unable to give informed consent, have limited life expectancy (<1 year) or are not available for follow-up will be excluded. Once patients have been identified, a recruitment letter signed by their family physician will be mailed to the patient. The letter will explain the study and ask the patient to contact the research coordinator if they are interested in participating. In addition, a study information letter will be handed to each identified patient by the family physician when the patient visits the clinic.

Intervention:

At study start, the intervention consisting of 1-page provider enabler, a point-of-care worksheet including a simplified algorithm and a patient workbook, will be distributed to each of the health care providers in practices randomized to the intervention by the research coordinator; this constitutes the provider-directed intervention phase (step 1). After 9 months, copies of the patient decision aid and workbook will be mailed to eligible patients; this constitutes the provider- and patient-directed phase (step 2). Based on the results of substudies 1 and 2, we will incorporate other components (e.g. training video) to overcome barriers to use and maximize implementation.

Control:

At study start, a hard copy of the executive summary of the CDA CPG will be distributed to each of the health care providers in practices randomized to the control by the research coordinator. After 9 months, copies of a CDA patient education pamphlet regarding diabetes self-management will be mailed to eligible patients. In addition, provider- and patient-directed guideline dissemination tools (not incorporating SDM) will also be publicly accessible from the CDA website.

Data collection:
At trial entry, sociodemographic information will be obtained (providers: age, gender, duration in practice, practice load, remuneration plan, academic/community, rural/urban, solo/group; patients: age, gender, ethnicity, age at diagnosis, comorbidities, educational attainment, annual income). Data on outcomes will be collected by participant-completed questionnaires completed either online or mailed at 6-month intervals and at study completion, corresponding to intervention steps 1 and 2 for a total of 3 data points over a 12-month period *(3.2 Timeline)*.

Outcome measures:
Initial aim: In order to assess intervention fidelity and the feasibility of conducting a larger clustered RCT, we will use structured exit questionnaires to assess for intervention use, the manner with which it was used (e.g. which components, which individuals, frequency), acceptability, reasons for use and non-use as well as barriers and facilitators to use. To assess the study's feasibility, we will keep detailed logs of all study processes to assess recruitment and retention, such as number of eligible patients, recruitment response rate, duration of recruitment period, questionnaire response rate, willingness of participants to be randomized, and willingness of clinicians to recruit patients.

Secondary aim: Primary outcome is decisional conflict; secondary outcomes are diabetes distress, chronic illness care, and quality of life. These outcomes will be assessed by well-validated patient-completed questionnaires (Appx3). These outcomes were selected because they are direct measures of knowledge use by patients that will allow us to better understand mediating variables of knowledge use such as patient activation, goal-setting, problem-solving, and decision support. Decisional conflict was chosen to allow us to assess the impact of our decision aid on the quality of the decision-making process, an important first measure of the effectiveness of a decision aid[2]and the SDM process[3]. Diabetes distress was selected as more holistic and patient-centred measure of knowledge use that uniquely acknowledges patient prioritization of health care goals [4,5]. Patients' and providers' intention to engage in SDM will be assessed with a 11-item questionnaire based on the Theory of Planned Behaviour[6]. Surrogate clinical outcomes (egA1c) were not chosen because of their limited relevance to the individualized nature of our intervention.

Randomization:
A biostatistician will simultaneously randomize and allocate practices to either intervention or control using computer-generated randomization in a 1:1 ratio. Investigators and research coordinators will be blinded to group allocation. Each practice will be given a code; the biostatistician will analyse the data blindly. Codes will be accessed after analysis is completed.

Analysis:
Initial aim: We will deem the study feasible if we are able to complete recruitment within a 6- to 9-month period and attain a response rate of ≥75% for questionnaire completion. This will inform whether we will proceed with a larger trial or if we need modify study processes prior to proceeding. In addition, standard deviations of our outcome measures will be used to estimate sample size of the larger trial.

Secondary aim: We hypothesize that patients in the intervention arm will have reduced decisional conflict and diabetes distress, and improved decision-making satisfaction, chronic care delivery and quality of life. Analysis will be done by intention-to-treat. The analysis to test this hypothesis will be carried out using multilevel hierarchical models (logistic regression for binary outcome and linear regression for continuous outcomes) to account for the clustered nature of the data. The group assignment will be a physician-level variable. We will also assess the impact of sociodemographic variables on these outcomes, as literature demonstrates that not all patients and providers want shared decision-[7]making[7-9].

References

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Statistical analysis plan:

Analysis will be done by intention-to-treat. For the primary and secondary outcomes, a linear mixed effect model will be used to analyze the total score for each scale where site was the random effect with adjustment for baseline value. The impact of sociodemographic variables on these outcomes (decisional conflict, diabetes distress, health-related quality of life, chronic illness care) will be assessed. Specifically, we will fit a main effects model that adjusted for age, sex, ethnicity, education, employment status and living arrangements as well as a fully-adjusted model that included all interactions between treatment and the preceding variables. P-values for the treatment effect in the baseline adjusted models use Satterthwaite's approximation for the denominator degrees of freedom while the tests of interactions (sub-group effects) employed likelihood ratio tests from a full maximum likelihood estimation [1]. Irrespective of the test result on sub-groups, the treatment effects will be then shown by subgroup, estimated from the second model specified above along with 95% confidence intervals and a p-value that tested each interaction in this fully-adjusted model. Descriptive statistics will be used to describe intervention effect by *MyDiabetesPlan* use. ANOVA will be used to assess difference in clinician's intention to practice IPSDM scores between intervention and control groups at baseline, 6 months and 12 months. Analysis will be performed in R version 3.5.2 [2] and used the packages lme4 (version 1.1-21) and lmerTest (version 3.1-0) [1] to fit and report the mixed-effect models.

References

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