BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-029105
Article Type:	Research
Date Submitted by the Author:	21-Jan-2019
Complete List of Authors:	Boehmer, Kasey R.; Mayo Clin, Dobler, Claudia; Mayo Clin, Knowledge and Evaluation Research Unit; 2. Evidence-Based Practice Center, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery Thota, Anjali; Mayo Clin, Knowledge and Evaluation Research Unit Branda, Megan; Mayo Clinic, Health Sciences Research Giblon, Rachel; Mayo Clin, 3. Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery Behnken, Emma; Mayo Clin, Knowledge and Evaluation Research Unit Organick, Paige; Mayo Clin, Knowledge and Evaluation Research Unit Allen, Summer; Mayo Clin, Knowledge and Evaluation Research Unit; Department of Family Medicine Shaw, Kevin; Mayo Clin, Knowledge and Evaluation Research Unit Montori, Victor; Mayo Clinic, Knowledge and Encounter Research Unit
Keywords:	patient-centered care, minimally disruptive medicine, healthcare communication, chronic disease, multimorbidity

Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and Feasibility Study of the ICAN Discussion Aid

Kasey R. Boehmer, PhD, MPH[1] (Boehmer.kasey@mayo.edu)
Claudia C. Dobler, MD, PhD[1,2] (Dobler.claudia@mayo.edu)
Anjali Thota, BA[1] (Thota.anjali@mayo.edu)
Megan Branda, MS[3] (Branda.megan@mayo.edu)
Rachel Giblon, MS[3] (Giblon.rachel@mayo.edu)
Emma Behnken, BA[1] (Behnken.emma@mayo.edu)
Paige Organick, BA[1] (Organick.paige@mayo.edu)
Summer V. Allen, MD[1,4] (Allen.summer@mayo.edu)
Kevin Shaw, BA[1] (Shaw.kevin@mayo.edu)
Victor M. Montori, MD, MSc[1] (Montori.victor@mayo.edu)

1. Knowledge and Evaluation Research Unit, Mayo Clinic, Rochester, Minnesota, USA
2. Evidence-Based Practice Center, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, USA
3. Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, USA
4. Department of Family Medicine, Mayo Clinic, Rochester, Minnesota

Corresponding Author:
Kasey R. Boehmer, PhD, MPH
Mayo Clinic
200 First Street SW
Rochester, MN 55905

Support: Funded by an internal Mayo Clinic Award from the Robert & Arlene Kogod Center for Aging

Prior Presentations: International Shared Decision Making Conference, Lyon, France, 2017; International Conference on Communication in Healthcare, Baltimore, MD, USA, 2017; North American Primary Care Research Group Conference, Montreal, Canada, 2017

Word Count: 2,680; 2 Figures, 4 Tables, 1 Appendix

Abstract

Purpose: To pilot test the impact of the ICAN Discussion Aid on clinical encounters.

Methods: A pre-post study involving 11 clinicians and 100 patients was conducted at two primary care clinics within a single health system in the Midwest. The study examined clinicians' perceptions about ICAN feasibility, patients' and clinicians' perceptions about encounter success, videographic differences in encounter topics, and medication adherence 6-months after an ICAN encounter.

Results: 40/40 control encounters and 45/60 ICAN encounters yielded usable data. Clinicians reported ICAN use was feasible. In ICAN encounters, patients discussed diet, being active, and taking medications more. Clinicians scored themselves poorer regarding visit success than their patients scored them; this effect was more pronounced in ICAN encounters. ICAN did not improve 6-month medication adherence or lengthen visits.

Conclusion: This pilot study suggests that using ICAN in primary care is feasible, efficient, and capable of modifying conversations. With lessons learned in this pilot, we are conducting a randomized trial of ICAN vs. usual care in diverse clinical settings.

Abstract Word Count: 167

Keywords: patient-centered care; minimally disruptive medicine; healthcare communication; chronic disease; multimorbidity

Trial Registration: NCT02390570; registered 2/19/2015

Article Summary: Strengths and limitations of this study

- Small before-after pilot study limiting the ability to draw statistical inferences that would be possible in a larger trial with a randomized design.
- Not powered to assess clinical significance for patient-reported outcomes nor prescription adherence; lack of difference found is not indicative of one not existing
- Single healthcare system in the Midwest with a fairly homogenous patient population limiting generalizability
- Small size was a strength in allowing us to pursue video-recording of all encounters, allowing deeper exploration of ICAN's impact on conversations and additional training needs for future implementation and testing

1. Introduction

Estimates in 2013 indicated that 117 million, or approximately half of adults in the U.S. had one or more chronic conditions,[1] while 26% of adults in the U.S. had multiple chronic conditions (MCC).[2] Patients living with chronic conditions must cope with the burden of illness and additionally invest time and energy to comprehend, manage, and access professional healthcare – the work of being a patient. If this work is not carefully managed and monitored, patients may experience treatment burden.[3,4]

Treatment burden often goes unnoticed, as clinical practice guidelines focus on managing individual conditions, without explicit consideration of co-morbidities or the patient's values, preferences, and context.[5] If implemented in this way, the application of all guideline recommendations may overwhelm patients [6-8]. Similarly, clinical practice does not often acknowledge patients' potentially limited capacity to handle complexity of life and healthcare work, which leads to the prescription of treatment plans that require capacity of patients and their caregivers that they may not have.[9,10]

This situation not only impacts patients and families, but has also led to burnt-out clinicians.[11] Beyond medical complexity described above, clinicians also need to consider non-medical complexity, (e.g., difficulty affording medications, unstable housing, and problematic family dynamics), and the body of literature is growing to show that clinicians have difficulty with conversations where medical and non-medical complexity intersect. [12-16]

The ICAN Discussion Aid (**Figure 1**) was developed using a robust user-centered design process, previously used to develop decision aids,[17 18] to address these problems. To date, it remains untested.

1.2. Aim

We aimed to evaluate the feasibility of using the ICAN Discussion Aid in primary care and to estimate its impact on clinical care, including patient and clinician-perceived success of visits, length of visits, and topics of conversation.

2. Methods

To pilot test the ICAN Discussion Aid, we conducted a pre-test versus post-test intervention study.

2.1. Ethics

All study procedures were approved by the Mayo Clinic IRB (14-008621); patient and clinician participants consented for data collection procedures.

2.2. Participant Eligibility and Recruitment

Clinicians were recruited from two clinical sites in the Midwest and were eligible for participation if they regularly saw patients with chronic conditions. Clinicians were consented for participation either at a lunch-hour clinical practice meeting or immediately before their first eligible patient. Adult patients were eligible if they had one or more chronic conditions, no major barriers to consent (e.g. cognitive impairment), and were seeing a clinician who had agreed to participate. Patients were approached immediately before the encounter with their clinician.

2.3 Study Procedures

After both clinician and patient were enrolled in the study, a trained study coordinator set up a small video camera (i.e., FlipCam, GoPro) to record the clinic visit. Patients and clinicians could turn the video camera off at any time if they felt uncomfortable, and the video camera was always turned around or off during physical exams. Following the encounter, both patient and

clinician were given a survey to complete immediately or return in a postage-paid return envelope. The study coordinator followed-up on surveys not returned within one week. The first 40 clinical encounters were usual care. After the first 40 encounters, clinicians were then trained during a standing meeting or individually on how to use the ICAN Discussion Aid. The remaining 60 clinical encounters were intended to be ICAN encounters.

2.4. Intervention: The ICAN Discussion Aid

The study coordinator provided instructions for the patient to complete the ICAN Discussion Aid (**Figure 1)** before the clinician entered the room. When the clinician entered the room, he or she would select one of three opening questions to elicit responses from the patient, and would then explore the information that the patient provided in ICAN by asking "What stands out to you on this sheet you filled?" Clinicians were instructed to discuss that issue alone and connect it to the reason for the visit that day. Clinical conversation was expected to proceed as usual with incorporation of the ICAN information.

2.5. Measures

Clinician degree, position, and gender were collected at baseline. Patient characteristics of age, sex and marital status were abstracted from the medical record. To assess *perceived success* of the encounter, we used the Consultation Care Measure (CCM), a valid and discriminating tool to measure communication and partnership within a single encounter, previously correlated with patient satisfaction, enablement, and reduced symptom burden.[19] The measure asks patients to what extent they agree with statements about the doctor such as he/she "was interested in what I thought the problem was."[19] For clinician surveys, we used a modified version of the patient CCM, adjusted to the clinician perspective, which was not previously

validated. For example, the patient might be asked the extent to which they felt the clinician "was careful to explain the plan of treatment." Whereas the clinician would be asked the extent to which they agreed with the statement that they felt that they "were careful to explain the plan of treatment." To assess *feasibility* of ICAN use, we asked clinicians to report how easy or difficult the aid was to use in their encounter on a 5-point scale, from very easy to very difficult. If clinicians marked difficult or very difficult, they were prompted to write a brief description of why. To assess *adherence, p*atients pharmaceutical records were collected as a means to provide estimates of baseline adherence amongst patients in this population, and of whether using ICAN potentially effects adherence through the tailoring of patient care plans to their life context. Given the hypothesis generating nature of the adherence data, the methods and results are provided in **Appendix 1.**

2.6. Videographic Coding Scheme

To assess ICAN's *impact on clinical conversation topics*, we created an a priori video coding scheme, in which we coded each instance where the following topics were brought up: family, friends, free time, faith, living situation, being active, rest, comfort, emotional life, senses, memory, eating well, taking medications, making appointments, getting to appointments, administrative treatment work (e.g., dealing with insurance/billing, communicating with pharmacies), prescribed behaviors (e.g. getting mammograms, exercising a certain number of minutes per week), and other treatment work (i.e, work that the patient was asked to do but that did not fit into these other categories). Life issues listed in the coding scheme were those shown on ICAN and previously illustrated as important components of patient capacity from earlier work.[18,20] Treatment burden issues listed in the coding scheme were derived from typical issues listed in the development of ICAN and a taxonomy of treatment burden.[18,21] We also coded for

opening questions typically used in ICAN, designed to elicit the existence of competing priorities that could potentially limit the capacity for self-care or treatment, sources of joy in patients' lives, and immediate concerns (medical and non-medical). To assess *impact on length of visit*, we compared lengths of video recording.

2.7. Analyses

All statistical analyses were conducted in SAS (SAS Institute Inc., Version9.4, Cary, NC, USA) and Stata (StataCorp, Release 15. College Station, TX). Videographic coding was done using Noldus Observer XT (version 11, Leesburg, VA). Patient and clinical encounter characteristics were compared between ICAN and control encounters using a t-test for continuous variables and a chi-square test for categorical variables. To explore differences in patient and clinician perceived success of an encounter, we subtracted unadjusted clinician scores from unadjusted patient scores, and tested for changes in the perceived success gap between ICAN and control encounters using a Wilcoxson Rank-Sum test. To test for differences across issues discussed in videos where patients and clinicians used ICAN versus those recorded in control encounters, we used a negative binomial model accounting for clustering within clinicians.

2.8 Patient and Public Involvement

The Knowledge and Evaluation Research Unit Patient Advisory Group participated in the design of the ICAN Discussion Aid, ensuring its relevance to patients living with chronic conditions and its ease of use. They were not consulted for the research design of the pilot study.

3. Results

Eleven clinicians were enrolled from two primary care clinics within the Midwest, United States starting in October 2015. Seven clinicians approached declined enrollment, without providing a reason. The clinicians were primarily female (N=7, 64%) and were primarily physicians, with one nurse practitioner and two physician assistants. Patient enrollment began October 2015 and ended February 2017. 100 patients consented to participate (ICAN n=60). Detailed enrollment information is depicted in **Figure 2**. Of the eleven clinicians participating, one had all control encounters and five had all ICAN encounters. Patient characteristics are depicted in **Table 1**. Encounter length did not significantly differ between ICAN and control encounters.

3.1. Clinician reported feasibility of ICAN

Clinicians found the tool feasible to use in the majority of encounters. 62% reported it very easy or easy, 32% reported it as neither easy nor difficult, and 5% reported it was difficult to use in that encounter. There were two encounters where it was reported as difficult by different clinicians. For one encounter the clinician stated, "Unfortunately, this made her appointment go over by about 30 minutes. It was good we discussed issues with the portal [*an online platform that allows patients to access their health information*] and her life and stressors but it wasn't a big concern (why it wasn't a reason for the appointment) but we spent a good deal of time on it." Upon further review of this video, it appears that the primary reason that the encounter lasted substantially longer than planned was a lack of fidelity to ICAN training. After the clinician asked the patient what stood out to her from ICAN, she continued to elicit information about each burden listed by the patient, rather than connect the patient's response to the remainder of the clinical visit. Addressing the two key issues the patient brought up, work

stress and being active, took approximately five and a half minutes in total. Following that, the clinician spent an additional five and a half minutes reviewing the other items on the tool.

In the second encounter, the clinician stated, "I enjoy the learning and conversation obtained from form [*sic*] but didn't have the extra time in schedule [*sic*] necessary to address each issue - easily added another 15-20 minutes to appointment." In this encounter, the patient indicated that her emotional life was both a source of satisfaction and a burden. The clinician enquired further and thus provided the patient with an opportunity to talk about her prolonged grief after the loss of her spouse and her concerns about possible depression. In response the clinician screened the patient for potential depression. Total time using the tool and discussing that issue took four minutes of the total visit. The patient was scheduled for a 45 minute general medical exam, and the total video recorded visit time was 26 minutes, which did not include the physical exam at the end of the encounter.

3.2. Survey Results

We did not find any items with significant differences between patients in either cohort for the consultation care measure (**Table 2**). When comparing patients and clinicians across the consultation care measure, among the items that overlapped, clinicians tended to score themselves poorer than patients. This was more prevalent when the ICAN tool was used (**Table 3**).

3.3. Videographic Results

Issues discussed during clinical encounters did significantly differ between ICAN and control encounters in multiple domains (**Table 4**). Specifically, discussions about being active, diet, and taking medications were discussed significantly more frequently in ICAN encounters.

Discussions about administrative treatment work, other treatment work, family, living arrangements, and comfort were discussed significantly less frequently in ICAN encounters. We noticed that often topics about family were used as conversation fillers in control encounters, whereas there may have been less room for this when patients were prompted to bring up issues that mattered most to them.

4. Discussion and Conclusion

4.1. Summary of Findings

Within this pilot trial, clinicians found the ICAN Discussion Aid to be a tool they could feasibly adopt into everyday practice and which did not impact the length of the visit. Patients discussed diet, being active, and taking medications more often in ICAN encounters. Additionally, clinicians elicited competing priorities using ICAN opening questions that were never elicited during the opening of control encounters. While clinicians rated the perceived success of their encounters poorer than their patients (CCM score), and the gap between patient and clinician perceived success was larger ICAN encounters, the difference was not significant. No difference was seen for adherence to prescription medications.

4.2. Limitations and Strengths

These findings cannot be interpreted without considering the limitations in this study design. First, this study was a small before-after pilot study which limits our ability to draw statistical inferences that would be possible in a larger trial with a randomized design. The study was not powered to assess clinical significance for patient-reported outcomes nor prescription adherence and a lack of difference found is not indicative of one not existing. Furthermore, the

study occurred within a single healthcare system in the Midwest with a fairly homogenous patient population of mostly high or middle socioeconomic status, which limits the generalizability of the specific changes in topics present in ICAN conversations versus usual care conversations. However, the small size of the study allowed us to pursue video-recording of all encounters, which allowed for deeper exploration of ICAN's impact on conversations and to point to additional needs for future implementation and testing of ICAN in practice that would have been more difficult in a larger multi-site study.

4.3. Practice Implications

Feasibility of ICAN use is an important finding on its own, given previously reported challenges by clinicians in providing patient-centered care and participating in shared decision making for populations living with MCC.[22] Furthermore, the difference in the topics brought up in ICAN encounters suggests that patients are indeed more likely to be able to voice their topics of choice, in an area where poor communication has been a noted frustration amongst patients.[23] Diet, being active, and taking medications are not surprising topics to be most important to patients in this setting and population (suburban, Midwest, academic medical center). However, these topics have been noted as important treatment burden factors for patients in other diverse samples; patients noted that they were aware their clinicians wanted them to eat healthier or exercise more frequently, but important barriers existed of which their clinicians were unaware.[24] Furthermore, in a previous study of patient-clinician concordance, patients were more likely than clinicians to rank being active as one of their top three health concerns.[25] Future research should examine whether the topics discussed more often are different in other clinical settings (e.g. rural and urban), with different populations (e.g. unsalaried clinicians, underserved patients), and what clinicians can do in clinical encounters with this information.

Examining the two encounters noted as difficult for clinicians yielded important information about ICAN implementation challenges. The encounter where additional time was used to discuss all ICAN items suggests that additional training may be needed for clinicians to illustrate how to connect the initial question of "What stands out to you?" to the clinical reason for the appointment, and how to continue the use of the discussion aid at future encounters. In the encounter in which the patient was able to discuss potential concerns of depression, the clinician noted that this added an additional 15 – 20 minutes to the encounter, whereas the actual discussion took less than five minutes. The perceived duration may have felt longer than the actual duration because of the heavy nature of the topic discussed. Past research in primary care patients with multi-morbidity has shown that clinician comfort level with these types of difficult topics is low and that in practicing a traditional "additive-sequential model," where each problem is treated independently and prioritized, these issues may never get acknowledged.[15,26] Therefore, the implementation of ICAN can provide an opportunity to train clinicians to address potentially difficult topics, manage their expectations of those discussions, and learn how to successfully have those conversations.

4.4. Conclusion

In conclusion, we successfully pilot tested the ICAN Discussion Aid in primary care encounters. This study illustrated that ICAN was perceived as feasible to implement in normal clinical practice, did not impact visit length, and impacted the conversation topics discussed in encounters. While patients perceived improved visit success with ICAN use, clinicians perceived worsened visit success. Clinical encounters that were noted as difficult to use ICAN point to additional ICAN training needs in future implementation and study settings.

Authors' contributions

KRB was responsible for study design, overall study execution, analysis, and the draft manuscript. CCD and AT conducted videographic analysis and provided critical revisions for the manuscript. MB and RG conducted statistical analysis, created tables, and drafted the statistical sections of the manuscript. EB was responsible for study coordination of the study and data collection procedures. PO assisted with data cleaning procedures, drafting of the manuscript, and critical revisions to the manuscript. SVA served as clinical champion for the study and provided critical revisions to the manuscript. KS provided revisions to the manuscript and data visualization. VMM assisted KRB with study design and oversight of the project.

Conflicts of Interests

The authors of this manuscript have no conflicts of interests to report.

Funding Statement

This research was supported in part by an internal award from the Mayo Clinic Robert and Arlene Kogod Center for Aging.

Included Figures

Figure 1: ICAN Discussion Aid

Figure 2: Detailed Enrollment Information

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Table 1: Patient and Encounter Characteristics^				
	ICAN (N=57*)	Pre-Intervention (N=40)	Total (N=97)	p value
Sex				0.09
Female	40 (70.2%)	34 (85.0%)	74 (76.3%)	
Age: Mean (SD)	62.7 (12.0)	66.8 (15.0)	64.4 (13.4)	0.05
Marital status				0.37
Divorced	11 (19.3%)	3 (7.5%)	14 (14.4%)	
Married	36 (63.2%)	27 (67.5%)	63 (64.9%)	
Single	5 (8.8%)	4 (10.0%)	9 (9.3%)	
Widowed	5 (8.8%)	6 (15.0%)	11 (11.3%)	
Length of encounter (minutes): Mean (SD)	31.6 (13.4)	34.5 (11.7)	32.9 (12.7)	0.25
Median (Q1, Q3)	31.3 (19, 41)	34.3 (25, 44)	33.6 (22, 42)	

^All enrolled patients.
*3 patients in intervention missing data on characteristics.

Table 2: CCM Patient Scores

Overall score	ICAN (N=42)	Pre-Intervention (N=39)	Total (N=81)
Mean (SD)	29.7 (11.0)	28.6 (12.4)	29.2(11.6)
Median (Range)	25 (21, 62)	23 (21, 74)	24 (21, 74)
Adjusted mean* (95% CI)	31.5 (24.6, 38.5)	34.6 (29.3, 42.9)	

*Adjusted by clinician clustering; lower scores = better

Table 3: Clinician – Patient Difference in individual CCM scores

	ICAN (N=38)*	Pre-Intervention (n=39)*	P-Value
1/E: Careful to explain	0.87 (0.52, 1.22)	0.64 (0.32, 0.96)	0.33
2/F: Was sympathetic	0.97 (0.57, 1.37)	0.54 (0.19, 0.89)	0.09
3/H: discussed & agreed together what problem was	0.97 (0.61, 1.33)	0.51 (0.19, 0.84)	0.047
4/K: discussed & agreed on plan of treatment	0.84 (0.51, 1.17)	0.59 (0.25, 0.93)	0.26
5/M: understood emotional needs	0.97 (0.43, 1.52)	0.77 (0.39, 1.15)	0.31
6/N: confident knows patient history	0.66 (0.23, 1.09)	0.77 (0.40, 1.14)	0.91
7/T: interested in effect of problem on family and personal life	0.68 (0.22, 1.15)	0.64 (0.27, 1.02)	0.73
8/U: interested in effect of problem on everyday life	0.82 (0.35, 1.29)	0.74 (0.39, 1.10)	0.60
Mean (95% CI), p-value Wilcoxon rank sum test			

* Difference in scores calculated as clinician score minus patient score for encounter. Higher scores correspond to lower performance on the CCM tool.

Table 4: Videographic Analysis of Issues Discussed by Patients and Clinicians

	Behaviors *	All Encounters (n=84/ICAN= 45)		Patients (n=84)		Clinicians (n=84)	
		IRR (95% CI)	P value	IRR (95% CI)	P value	IRR (95% CI)	P value
More likely with ICAN	**Being active**	**1.52 (1.09, 2.11)**	**0.01**	**1.58 (1.12, 2.22)**	**0.008**	1.45 (0.95, 2.21)	0.09
	Taking medications	1.22 (0.99, 1.51)	0.06	**1.42 (1.20, 1.67)**	**<.0001**	1.12 (0.85, 1.46)	0.42
	Diet	**2.02 (1.22, 3.32)**	**0.005**	**2.32 (1.39, 3.88)**	**0.001**	1.61 (0.93, 2.79)	0.09
	Competing priorities	**14.46 (4.00, 52.24)**	**<.0001**	---**	---	**10.91 (3.63, 32.73)**	**<.0001**
Less Likely with ICAN	**Other admin**	**0.56 (0.39, 0.82)**	**0.002**	0.74 (0.48, 1.13)	0.16	**0.47 (0.33, 0.69)**	**<.0001**
	Family	**0.57 (0.36, 0.90)**	**0.02**	0.66 (0.42, 1.03)	0.05	**0.46 (0.28, 0.75)**	**0.002**
	Faith	**0.59 (0.42, 0.82)**	**0.002**	0.78 (0.44, 1.39)	0.41	0.36 (0.12, 1.05)	0.06
	Senses	**0.55 (0.30, 1.00)**	**0.05**	0.65 (0.35, 1.22)	0.18	**0.44 (0.23, 0.87)**	**0.02**
No Difference with ICAN	Other treatment work	0.90 (0.65, 1.24)	0.52	1.07 (0.71, 1.63)	0.74	0.77 (0.59, 1.01)	0.06
	Immediate concerns	1.11 (0.69, 1.76)	0.68	1.62 (0.86, 3.06)	0.14	0.90 (0.60, 1.37)	0.64
	Joy	---**	---	---**	---	---**	---
	Where I live	0.82 (0.50, 1.35)	0.44	1.09 (0.66, 1.80)	0.75	0.58 (0.32, 1.04)	0.07
	Comfort	0.76 (0.50, 1.16)	0.20	0.90 (0.62, 1.33)	0.61	0.63 (0.39, 1.01)	0.05
	Free time	1.08 (0.54, 2.16)	0.82	1.20 (0.60, 2.40)	0.61	0.96 (0.45, 2.04)	0.92
	Making appointments	0.76 (0.50, 1.16)	0.21	0.77 (0.49, 1.23)	0.27	0.75 (0.49, 1.15)	0.18
	Prescribed behaviors	0.84 (0.45, 1.58)	0.59	0.96 (0.57, 1.64)	0.89	0.80 (0.40, 1.61)	0.53
	Friends	0.75 (0.33, 1.66)	0.47	0.65 (0.30, 1.40)	0.27	1.41 (0.52, 3.75)	0.49
	Getting to appointments	1.24 (0.74, 2.08)	0.41	1.34 (0.76, 2.36)	0.32	1.09 (0.60, 2.00)	0.78
	Work	0.85 (0.60, 1.220	0.39	1.05 (0.75, 1.47)	0.80	0.62 (0.38, 1.02)	0.06
	Rest	0.89 (0.52, 1.54)	0.68	0.92 (0.52, 1.59)	0.75	0.87 (0.46, 1.64)	0.67
	Emotional life	1.23 (0.54, 2.80)	0.63	1.56 (0.64, 3.83)	0.33	1.03 (0.41, 2.59)	0.95
	Volunteer	0.85 (0.30, 2.38)	0.76	0.57 (0.16, 2.04)	0.39	---**	---
	Personal meaning	2.39 (0.18, 32.56)	0.51	2.39 (0.18, 31.56)	0.51	---**	---
	School	---**	---	---**	---	---**	---
	Memory	1.98 (0.70, 5.63)	0.20	2.41 (0.71, 8.25)	0.1596	0.80 (0.30, 2.13)	0.65

IRR = Incidence Rate Ratio; >1 means more occurrences in ICAN encounters, <1 fewer occurrences in ICAN encounters
*Adjusted for gender, age at enrollment, length of encounter and clustering around shared clinicians
** Insufficient data for analysis

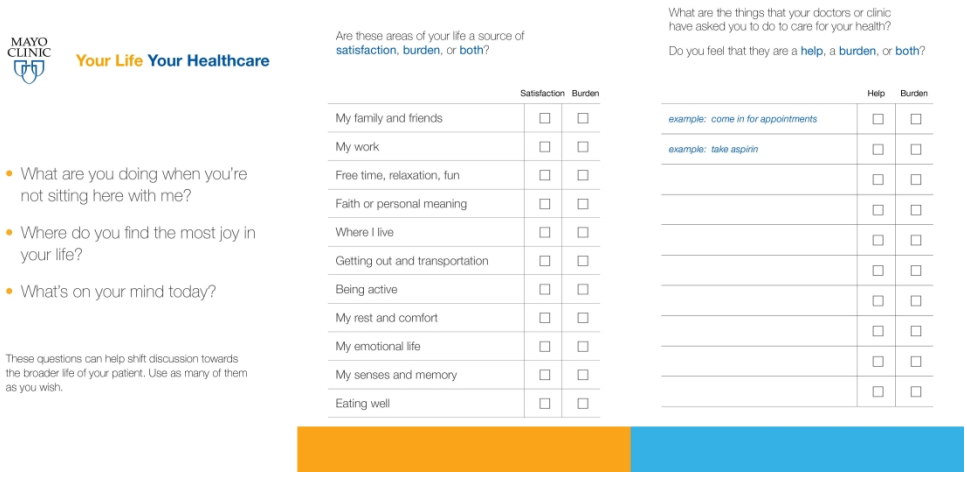

Figure 1: ICAN Discussion Aid

419x215mm (300 x 300 DPI)

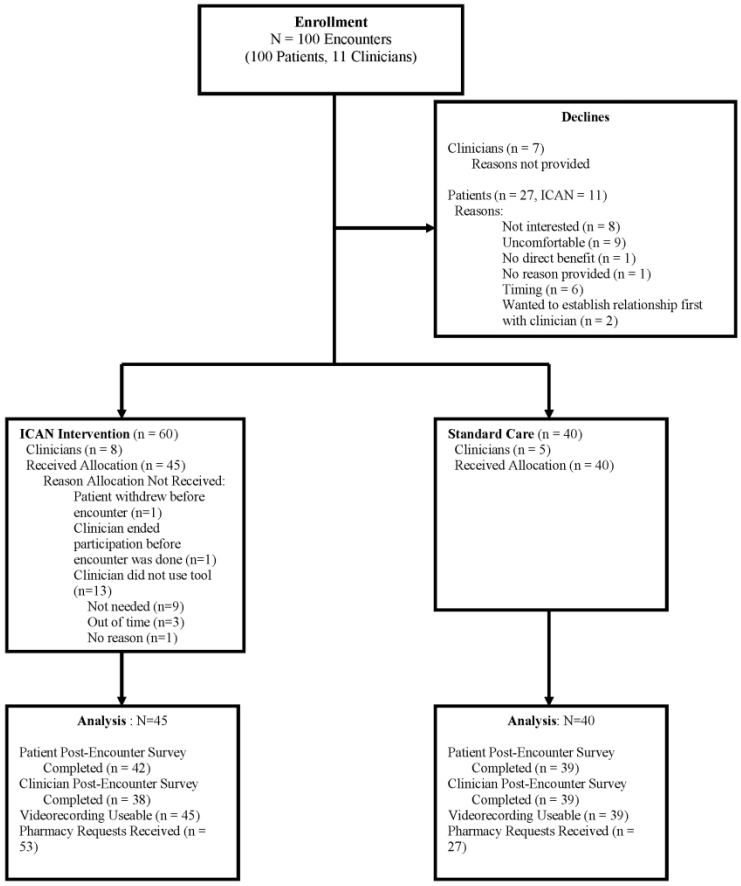

Figure 2: Detailed Enrollment Information

215x279mm (300 x 300 DPI)

Appendix 1: Pharmaceutical prescription methods and results

Measure

Patients' prescriptions that had been filled were obtained from their pharmacies directly. We collected information on patients' filled prescriptions six months prior to enrollment to six months post-enrollment. Adherence to treatment was assessed for the six months post-enrollment by calculating the percentage of days out of the 180 day period for which a patient had a filled prescription.[23] Medications to treat chronic conditions were considered for inclusion in analysis.

Appendix Table 1: Included Medications

Medication Class	Medication Name
ACE inhibitor	Enalapril Maleate
	Lisinopril
	Ramipril
Alpha blocker	Tamsulosin
	Tamsulosin HCL
Alpha1 adrenergic blocker	Doxazosin Mesylate
Alpha2 delta ligand	Lyrica
Aminoketone antidepressant	Bupropion
	Bupropion HCL
	Bupropion HCL ER
	Bupropion XL
	SR Bupropion
Angiotensin receptor blocker (ARB)	Candesartan
	Lorsartan Potassium
	Losartan
	Losartan -HCTZ
	Losartan HCTZ
	Losartan Potassium
	Losartan-HCTZ
	Valsartan
Antiandrogen	Bicalutamide
Antiarrhythmic drug	Amiodarone
	Flecainide Acetate

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
Anticoagulant	**Enoxaparin Sodium**
	Jantoven
	Warfarin Sodium
	Xarelto
Anticonvulsant	**Carbamazepine**
	Carbamazepine ER
	Gabapentin
	Lamotrigine
	Topiramate
	Zonisamide
Anxiolytic antianxiety agent	**Buspirone**
Atypical antipsychotic	**Latuda**
	Quetiapine
	Quetiapine Fumarate
Beta blocker	**Atendlol Chlorthalidone**
	Atenolol
	Bisoprolol
	Carvedilol
	ER Metoprolol
	Metoprolol ER
	Metoprolol ER Succinate
	Metoprolol SUCC ER
	Metoprolol Tart
	Metoprolol Tartrate
	Metoprololhydrochloroth
	Timolol Maleate
Biguanide	**Metforman**
	Metformin
	Metformin ER
	Metformin HCL

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
	Metformin HCL ER
	metformin
Bisphosphonate	**Alendronate**
	Alendronate Sodium
Calcium channel blocker	**Amlodipine**
	Amlodipine Besylate
	Diltiazem HCL ER
	Nifedipine
	Verapamil HCR ER
Central alpha agonist	**Clonidine HCL**
Central muscle relaxant	**Methocarbamol**
Class 1b antiarrhythmic drug	**Lidocaine**
DDP4 inhibitor + biguanide	**Janumet XR**
Dibenzazepine	**Tegretol XR**
Digitalis glycoside	**Digoxin**
Disease modifying antirheumatic drug (DMARD)	**Hydroxychloroquine Sulfate**
Diuretic	**Hydrochilorothiazide**
	Hydrochlorothiazide
	Metolazone
Fibric acid	**Fenofibrate**
	Fenofibrate Micronized
Janus kinase (JAK) inhibitors	**Xeljanz**
Leukotriene receptor antagonists	**Montelukast Sodium**
Loop diuretic	**Furobemide**
	Furosemide
	Torsemide
Nitrate	**Isosorb Mono ER**
	Isosorbide MN ER
Nonergoline dopamine agonist	**Pramipexole**
Oral diuretic	**Triamterene-HCTZ**

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
P2Y12 inhibitor	**Clopidogrel**
	Clopidogrel Bisulfate
Phenylpiperazine antidepressant	**Nefazodone HCL**
Phosphodiesterase 4 (PDE4) inhibitors	**Otezla**
Potassium sparing diuretic	**Spironolactone**
SNRI	**Desvenlafaxine ER**
	Duloxetine DR
	Duloxetine HCL
	Duloxetine Hcl
	ER Venlafaxine
	Escitalopram Oxalate
	Venafaxine XR
	Venlafaxin XR
	Venlafaxine ER
	Venlafaxine HCL ER
	Venlafaxine XR
SSRI	**Citalopram**
	Citalpram
	Fluoxetine
	Fluoxetine HCL
	Paroxetine
	Paroxetine HCL
	Sertraline
	Sertraline HCL
Selective estrogen receptor modulator (SERM)	**Raloxifene HCL**
	Tamoxifen
Statin	**Atorvastatin**
	Atorvastatin Calcium
	Locastatin
	Lovastatin

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
	Pravastatin Sodium
	Rosuvastatin Calcium
	Simvastatin
	Vytorin
Sulfonylurea	**Climepiride**
	Glimepiride
	Glipizide
	Glipizide ER
	Glipizide XL
Tetracyclic antidepressant	**Mirtazapine**
Thiazide diuretic	**Chlorthalidone**
Thyroxine; T4 (synthetic)	**Levothroxine**
	Levothyroxine
	Levothyroxine SOD
	Synthroid
Triazolopyridine antidepressant	**Trazodone HCL**
Tricyclic antidepressant	**Amitriptyline HCL**
	Cyclobenzaprine HCL
	Cyclovbenzaprine HCL
	Cyclovenzaprine HCL
	Nortiptyline
	Nortriptyline
	Nortriptyline HCL
Triiodothyronine	**Liothyronine Sodium**
Valeric acid	**Gemfibrozil**
Missing	**Missing**
Other / Unknown	**Amsulosin**
	Isometh-apap-dichlor-
	Metromin HCL
	Oxycodone 5MG IR Tabs

Statistical Analysis

Adherence to medications was assessed by medication class (i.e. if patient had multiple medications within a class, average adherence was calculated). Adherence was modeled using a hierarchical generalized linear model where the outcome was a patients' medication class adherence six months post enrollment. The model was clustered by patient, as patients could have multiple classes of medication, and adjusted by their adherence to the medication class in the six months prior to enrollment and intervention arm. Patients who did not have the medication class in the prior period were set to zero for baseline and a missing indicator was assessed in the model to address this. Patients with missing pharmacy data (e.g. their pharmacy

Adherence Results

Similar rates of medication counts, medication classes and adherence were seen between groups in the six months prior to the encounter of interest (76% of days covered in patients in the ICAN group vs. 71% control)was unreachable for data request) were not included in the analysis.

Appendix Table 2: Analysis of percent of days covered of medication classes by intervention.

	ICAN (N=53)	Pre-Intervention (N=27)	p value
Count of medications prior to encounter			0.57
Mean (SD)	3.6 (2.6)	4.2 (3.3)	
Median (IQR)	3 (2, 5)	4 (2, 5)	
Count of medication classes prior to encounter			0.54
Mean (SD)	3.4 (2.3)	3.9 (2.9)	
Median	3 (1, 5)	4 (2, 5)	
Adherence (PDC) prior to encounter			0.94
Mean (95% CI)	55% (50, 60)	54% (50, 60)	
Count of medications post encounter			0.37
Mean (SD)	3.8 (2.5)	4.1 (2.0)	
Median	3 (2, 5)	4 (3, 5)	
Count of medication classes post encounter			0.36
Mean (SD)	3.6 (2.3)	3.9 (1.8)	
Median	3 (2, 5)	4 (3, 5)	

Appendix Table 2: Analysis of percent of days covered of medication classes by intervention.			
	ICAN (N=53)	Pre-Intervention (N=27)	p value
Adherence (PDC) post encounter			0.56
Mean (95% CI)	75% (70, 80)	71% (60, 80)	
Adjusted adherence (PDC) post encounter^			0.43
Mean (95% CI)	76% (70, 80)	72% (60, 80)	

Acronym: PDC Percent of Days Covered

* Prior and post encounter periods are each 6 months long.

^ ANCOVA with random effect of clinician and adjusted by prior 6 months adherence and intervention.

BMJ Open

Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and Feasibility Study of the ICAN Discussion Aid

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-029105.R1
Article Type:	Research
Date Submitted by the Author:	28-May-2019
Complete List of Authors:	Boehmer, Kasey R.; Mayo Clin, Dobler, Claudia; Mayo Clin, Knowledge and Evaluation Research Unit; 2. Evidence-Based Practice Center, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery Thota, Anjali; Mayo Clin, Knowledge and Evaluation Research Unit Branda, Megan; Mayo Clinic, Health Sciences Research Giblon, Rachel; Mayo Clin, 3. Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery Behnken, Emma; Mayo Clin, Knowledge and Evaluation Research Unit Organick, Paige; Mayo Clin, Knowledge and Evaluation Research Unit Allen, Summer; Mayo Clin, Knowledge and Evaluation Research Unit; Department of Family Medicine Shaw, Kevin; Mayo Clin, Knowledge and Evaluation Research Unit Montori, Victor; Mayo Clinic, Knowledge and Encounter Research Unit
Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Communication
Keywords:	patient-centered care, minimally disruptive medicine, healthcare communication, chronic disease, multimorbidity

Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and Feasibility Study of the ICAN Discussion Aid

Kasey R. Boehmer, PhD, MPH[1] (Boehmer.kasey@mayo.edu)
Claudia C. Dobler, MD, PhD[1,2] (Dobler.claudia@mayo.edu)
Anjali Thota, BA[1] (Thota.anjali@mayo.edu)
Megan Branda, MS[3] (Branda.megan@mayo.edu)
Rachel Giblon, MS[3] (Giblon.rachel@mayo.edu)
Emma Behnken, BA[1] (Behnken.emma@mayo.edu)
Paige Organick, BA[1] (Organick.paige@mayo.edu)
Summer V. Allen, MD[1,4] (Allen.summer@mayo.edu)
Kevin Shaw, BA[1] (Shaw.kevin@mayo.edu)
Victor M. Montori, MD, MSc[1] (Montori.victor@mayo.edu)

1. Knowledge and Evaluation Research Unit, Mayo Clinic, Rochester, Minnesota, USA
2. Evidence-Based Practice Center, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, USA
3. Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, USA
4. Department of Family Medicine, Mayo Clinic, Rochester, Minnesota

Corresponding Author:
Kasey R. Boehmer, PhD, MPH
Mayo Clinic
200 First Street SW
Rochester, MN 55905

Support: Funded by an internal Mayo Clinic Award from the Robert & Arlene Kogod Center for Aging

Prior Presentations: International Shared Decision Making Conference, Lyon, France, 2017; International Conference on Communication in Healthcare, Baltimore, MD, USA, 2017; North American Primary Care Research Group Conference, Montreal, Canada, 2017

Word Count: 2,680; 2 Figures, 4 Tables, 1 Appendix

Abstract

Purpose: To pilot test the impact of the ICAN Discussion Aid on clinical encounters.

Methods: A pre-post study involving 11 clinicians and 100 patients was conducted at two primary care clinics within a single health system in the Midwest. The study examined clinicians' perceptions about ICAN feasibility, patients' and clinicians' perceptions about encounter success, videographic differences in encounter topics, and medication adherence 6-months after an ICAN encounter.

Results: 40/40 control encounters and 45/60 ICAN encounters yielded usable data. Clinicians reported ICAN use was feasible. In ICAN encounters, patients discussed diet, being active, and taking medications more. Clinicians scored themselves poorer regarding visit success than their patients scored them; this effect was more pronounced in ICAN encounters. ICAN did not improve 6-month medication adherence or lengthen visits.

Conclusion: This pilot study suggests that using ICAN in primary care is feasible, efficient, and capable of modifying conversations. With lessons learned in this pilot, we are conducting a randomized trial of ICAN vs. usual care in diverse clinical settings.

Abstract Word Count: 167

Keywords: patient-centered care; minimally disruptive medicine; healthcare communication; chronic disease; multimorbidity

Trial Registration: NCT02390570; registered 2/19/2015

Article Summary: Strengths and limitations of this study

- Small before-after pilot study limiting the ability to draw statistical inferences that would be possible in a larger trial with a randomized design.
- Not powered to assess clinical significance for patient-reported outcomes nor prescription adherence; lack of difference found is not indicative of one not existing
- Single healthcare system in the Midwest with a fairly homogenous patient population limiting generalizability
- Small size was a strength in allowing us to pursue video-recording of all encounters, allowing deeper exploration of ICAN's impact on conversations and additional training needs for future implementation and testing

1. Introduction

Estimates in 2013 indicated that 117 million, or approximately half of adults in the U.S. had one or more chronic conditions,[1] while 26% of adults in the U.S. had multiple chronic conditions (MCC).[2] Patients living with chronic conditions must cope with the burden of illness and additionally invest time and energy to comprehend, manage, and access professional healthcare – the work of being a patient. If this work is not carefully managed and monitored, patients may experience treatment burden.[3,4]

Treatment burden often goes unnoticed, as clinical practice guidelines focus on managing individual conditions, without explicit consideration of co-morbidities or the patient's values, preferences, and context.[5] If implemented in this way, the application of all guideline recommendations may overwhelm patients [6-8]. Similarly, clinical practice does not often acknowledge patients' potentially limited capacity to handle complexity of life and healthcare work, which leads to the prescription of treatment plans that require capacity of patients and their caregivers that they may not have.[9,10]

This situation not only impacts patients and families, but has also led to burnt-out clinicians.[11] Beyond medical complexity described above, clinicians also need to consider non-medical complexity, (e.g., difficulty affording medications, unstable housing, and problematic family dynamics), and the body of literature is growing to show that clinicians have difficulty with conversations where medical and non-medical complexity intersect. [12-16]

The ICAN Discussion Aid (**Figure 1**) was developed to address these problems, with the aim of enabling the discussion of patient workload, capacity, and treatment burden within the time constraints of busy primary care visits.[17] The process to develop ICAN is described in full elsewhere.[17] Briefly, it was developed using a robust, iterative user-centered design process,

previously used to develop decision aids[18] and was grounded in the Cumulative Complexity Model, which states that patients living with chronic illness must enact both patient and life work with limited capacity.[19] When workload exceeds patient capacity, it affects patients' abilities to access and use healthcare and enact self-care, in turn effecting their health outcomes.[19] In addition to worsening health outcomes, unaddressed workload-capacity imbalance can lead to a vicious cycle of added treatment burden and illness burden.[19]

To date, the ICAN Discussion Aid remains untested in terms of its impact on the discussion of patient workload, capacity, and treatment burden in the clinical encounter. We hypothesize that if ICAN proves feasible in busy primary care and positively impacts the clinical encounter with greater discussion of patients' context, it could spark treatment plans that better fit patients' lives, with downstream impact on patient health outcomes and quality of life.

1.2. Aim

We aimed to evaluate the feasibility of using the ICAN Discussion Aid in primary care and to estimate its impact on clinical care, including patient and clinician-perceived success of visits, length of visits, and topics of conversation.

2. Methods

To pilot test the ICAN Discussion Aid, we conducted a pre-test versus post-test intervention study.

2.1. Ethics

All study procedures were approved by the Mayo Clinic IRB (14-008621); patient and clinician participants consented for data collection procedures.

2.2. Participant Eligibility and Recruitment

Clinicians were recruited from two clinical sites in the Midwest and were eligible for participation if they regularly saw patients with chronic conditions. Clinicians were consented for participation either at a lunch-hour clinical practice meeting or immediately before their first eligible patient. Adult patients were eligible if they had one or more chronic conditions, no major barriers to consent (e.g. cognitive impairment), and were seeing a clinician who had agreed to participate. Patients were approached immediately before the encounter with their clinician.

2.3 Study Procedures

After both clinician and patient were enrolled in the study, a trained study coordinator set up a small video camera (i.e., FlipCam, GoPro) to record the clinic visit. Patients and clinicians could turn the video camera off at any time if they felt uncomfortable, and the video camera was always turned around or off during physical exams. Following the encounter, both patient and clinician were given a survey to complete immediately or return in a postage-paid return envelope. The study coordinator followed-up on surveys not returned within one week. The first 40 clinical encounters were usual care. After the first 40 encounters, clinicians were then trained during a standing meeting or individually on how to use the ICAN Discussion Aid. The remaining 60 clinical encounters were intended to be ICAN encounters.

2.4. Intervention: The ICAN Discussion Aid

The study coordinator provided instructions for the patient to complete the ICAN Discussion Aid (**Figure 1)** before the clinician entered the room. When the clinician entered the room, he or she would select one of three opening questions to elicit responses from the patient, and would then explore the information that the patient provided in ICAN by asking "What

stands out to you on this sheet you filled?" Clinicians were instructed to discuss that issue alone and connect it to the reason for the visit that day. Clinical conversation was expected to proceed as usual with incorporation of the ICAN information.

2.5. Measures

Clinician degree, position, and gender were collected at baseline. Patient characteristics of age, sex and marital status were abstracted from the medical record. To assess *perceived success* of the encounter, we used the Consultation Care Measure (CCM), a valid and discriminating tool to measure communication and partnership within a single encounter, previously correlated with patient satisfaction, enablement, and reduced symptom burden.[20] The measure asks patients to what extent they agree with statements about the doctor such as he/she "was interested in what I thought the problem was."[20] For clinician surveys, we used a modified version of the patient CCM, adjusted to the clinician perspective, which was not previously validated. For example, the patient might be asked the extent to which they felt the clinician "was careful to explain the plan of treatment." Whereas the clinician would be asked the extent to which they agreed with the statement that they felt that they "were careful to explain the plan of treatment." To assess *feasibility* of ICAN use, we asked clinicians to report how easy or difficult the aid was to use in their encounter on a 5-point scale, from very easy to very difficult. If clinicians marked difficult or very difficult, they were prompted to write a brief description of why. To assess *adherence, p*atients pharmaceutical records were collected as a means to provide estimates of baseline adherence amongst patients in this population, and of whether using ICAN potentially effects adherence through the tailoring of patient care plans to their life context. Given the hypothesis generating nature of the adherence data, the methods and results are provided in **Appendix 1.**

2.6. Videographic Coding Scheme

To assess ICAN's *impact on clinical conversation topics*, we created an a priori video coding scheme, in which we coded each instance where the following topics were brought up: family, friends, free time, faith, living situation, being active, rest, comfort, emotional life, senses, memory, eating well, taking medications, making appointments, getting to appointments, administrative treatment work (e.g., dealing with insurance/billing, communicating with pharmacies), prescribed behaviors (e.g. getting mammograms, exercising a certain number of minutes per week), and other treatment work (i.e, work that the patient was asked to do but that did not fit into these other categories). Life issues listed in the coding scheme were those shown on ICAN and previously illustrated as important components of patient capacity from earlier work.[17,21] Treatment burden issues listed in the coding scheme were derived from typical issues listed in the development of ICAN and a taxonomy of treatment burden.[17,22] We also coded for opening questions typically used in ICAN, designed to elicit the existence of competing priorities that could potentially limit the capacity for self-care or treatment, sources of joy in patients' lives, and immediate concerns (medical and non-medical). To assess *impact on length of visit*, we compared lengths of video recording.

2.7. Analyses

All statistical analyses were conducted in SAS (SAS Institute Inc., Version9.4, Cary, NC, USA) and Stata (StataCorp, Release 15. College Station, TX). Videographic coding was done using Noldus Observer XT (version 11, Leesburg, VA). Patient and clinical encounter characteristics were compared between ICAN and control encounters using a t-test for continuous variables and a chi-square test for categorical variables. To explore differences in

patient and clinician perceived success of an encounter, we subtracted unadjusted clinician scores from unadjusted patient scores, and tested for changes in the perceived success gap between ICAN and control encounters using a Wilcoxson Rank-Sum test. To test for differences across issues discussed in videos where patients and clinicians used ICAN versus those recorded in control encounters, we used a negative binomial model accounting for clustering within clinicians.

2.8 Patient and Public Involvement

The Knowledge and Evaluation Research Unit Patient Advisory Group participated in the design of the ICAN Discussion Aid, ensuring its relevance to patients living with chronic conditions and its ease of use. They were not consulted for the research design of the pilot study.

3. Results

Eleven clinicians were enrolled from two primary care clinics within the Midwest, United States starting in October 2015. Seven clinicians approached declined enrollment, without providing a reason. The clinicians were primarily female (N=7, 64%) and were primarily physicians, with one nurse practitioner and two physician assistants. Patient enrollment began October 2015 and ended February 2017. 100 patients consented to participate (ICAN n=60). Detailed enrollment information is depicted in **Figure 2**. Of the eleven clinicians participating, one had all control encounters and five had all ICAN encounters. Patient characteristics are depicted in **Table 1**. Encounter length did not significantly differ between ICAN and control encounters.

3.1. Clinician reported feasibility of ICAN

Clinicians found the tool feasible to use in the majority of encounters. 62% reported it very easy or easy, 32% reported it as neither easy nor difficult, and 5% reported it was difficult to use in that encounter. There were two encounters where it was reported as difficult by different clinicians. For one encounter the clinician stated, "Unfortunately, this made her appointment go over by about 30 minutes. It was good we discussed issues with the portal [*an online platform that allows patients to access their health information*] and her life and stressors but it wasn't a big concern (why it wasn't a reason for the appointment) but we spent a good deal of time on it." Upon further review of this video, it appears that the primary reason that the encounter lasted substantially longer than planned was a lack of fidelity to ICAN training. After the clinician asked the patient what stood out to her from ICAN, she continued to elicit information about each burden listed by the patient, rather than connect the patient's response to the remainder of the clinical visit. Addressing the two key issues the patient brought up, work stress and being active, took approximately five and a half minutes in total. Following that, the clinician spent an additional five and a half minutes reviewing the other items on the tool.

In the second encounter, the clinician stated, "I enjoy the learning and conversation obtained from form [*sic*] but didn't have the extra time in schedule [*sic*] necessary to address each issue - easily added another 15-20 minutes to appointment." In this encounter, the patient indicated that her emotional life was both a source of satisfaction and a burden. The clinician enquired further and thus provided the patient with an opportunity to talk about her prolonged grief after the loss of her spouse and her concerns about possible depression. In response the clinician screened the patient for potential depression. Total time using the tool and discussing that issue took four minutes of the total visit. The patient was scheduled for a 45 minute general

medical exam, and the total video recorded visit time was 26 minutes, which did not include the physical exam at the end of the encounter.

3.2. Survey Results

We did not find any items with significant differences between patients in either cohort for the consultation care measure (**Table 2**). When comparing patients and clinicians across the consultation care measure, among the items that overlapped, clinicians tended to score themselves poorer than patients. This was more prevalent when the ICAN tool was used (**Table 3**).

3.3. Videographic Results

Issues discussed during clinical encounters did significantly differ between ICAN and control encounters in multiple domains (**Table 4**). Specifically, discussions about being active, diet, and taking medications were discussed significantly more frequently in ICAN encounters. Discussions about administrative treatment work, other treatment work, family, living arrangements, and comfort were discussed significantly less frequently in ICAN encounters. We noticed that often topics about family were used as conversation fillers in control encounters, whereas there may have been less room for this when patients were prompted to bring up issues that mattered most to them.

4. Discussion and Conclusion

4.1. Summary of Findings

Within this pilot trial, clinicians found the ICAN Discussion Aid to be a tool they could feasibly adopt into everyday practice and which did not impact the length of the visit. Patients discussed diet, being active, and taking medications more often in ICAN encounters. Additionally, clinicians elicited competing priorities using ICAN opening questions that were never elicited during the opening of control encounters. While clinicians rated the perceived success of their encounters poorer than their patients (CCM score), and the gap between patient and clinician perceived success was larger ICAN encounters, the difference was not significant. No difference was seen for adherence to prescription medications.

4.2. Limitations and Strengths

These findings cannot be interpreted without considering the limitations in this study design. First, this study was a small before-after pilot study which limits our ability to draw statistical inferences that would be possible in a larger trial with a randomized design. The study was not powered to assess clinical significance for patient-reported outcomes nor prescription adherence and a lack of difference found is not indicative of one not existing. Furthermore, the study occurred within a single healthcare system in the Midwest with a fairly homogenous patient population of mostly high or middle socioeconomic status, which limits the generalizability of the specific changes in topics present in ICAN conversations versus usual care conversations. However, the small size of the study allowed us to pursue video-recording of all encounters, which allowed for deeper exploration of ICAN's impact on conversations and to point to additional needs for future implementation and testing of ICAN in practice that would have been more difficult in a larger multi-site study.

4.3. Practice Implications

Feasibility of ICAN use is an important finding on its own, given previously reported challenges by clinicians in providing patient-centered care and participating in shared decision making for populations living with MCC.[23] Furthermore, the difference in the topics brought up in ICAN encounters suggests that patients are indeed more likely to be able to voice their topics of choice, in an area where poor communication has been a noted frustration amongst patients.[24] Diet, being active, and taking medications are not surprising topics to be most important to patients in this setting and population (suburban, Midwest, academic medical center). However, these topics have been noted as important treatment burden factors for patients in other diverse samples; patients noted that they were aware their clinicians wanted them to eat healthier or exercise more frequently, but important barriers existed of which their clinicians were unaware.[25] Furthermore, in a previous study of patient-clinician concordance, patients were more likely than clinicians to rank being active as one of their top three health concerns.[26] Future research should examine whether the topics discussed more often are different in other clinical settings (e.g. rural and urban), with different populations (e.g. unsalaried clinicians, underserved patients), and what clinicians can do in clinical encounters with this information.

Ultimately, the discussion of topics of greater importance to patients and their competing priorities is important as it could lead to better tailoring of treatment plans to patients' context, improving patients' workload-capacity balance in managing chronic illness. As mentioned earlier, the Cumulative Complexity Model postulates that workload-capacity balance impacts patients' abilities to access and use healthcare and enact self-care, with downstream impact on their health outcomes.[19] Furthermore, communication models, such as the one proposed by Street et al. have postulated the pathways from patient-clinician communication to patient outcomes.[27] For example, Street's model illustrates that communication functions supported by ICAN such as

managing uncertainty, fostering relationships, and enabling self-management can impact proximal outcomes such as patient trust and "feeling known," with downstream consequences on self-care skills, adherence, and ultimately health outcomes.[27] ICAN is a general discussion aid for use in chronic illness, intended to provide insight into the personal, social, material, and spiritual aspects of the patient's situation; it can be used in conjunction with the many available decision-specific conversation aids.[28] For example, an ICAN conversation may illuminate that a patient finds their overall medication regimen particularly burdensome, and this may spark a treatment-specific conversation about choosing a different treatment in replacement of a current one or inform the decision to add or not add another medication to the list. A good example of the use of ICAN and a treatment decision aid is available on the web.[29] Used in this way, clinicians may fully understand patients' competing priorities as well as treatment-specific values and preferences, and therefore, be able to co-create with them treatment plans that fit their context and allow them to lead quality lives to the fullest extent.

Examining the two encounters noted as difficult for clinicians yielded important information about ICAN implementation challenges. The encounter where additional time was used to discuss all ICAN items suggests that additional training may be needed for clinicians to illustrate how to connect the initial question of "What stands out to you?" to the clinical reason for the appointment, and how to continue the use of the discussion aid at future encounters. In the encounter in which the patient was able to discuss potential concerns of depression, the clinician noted that this added an additional 15 – 20 minutes to the encounter, whereas the actual discussion took less than five minutes. The perceived duration may have felt longer than the actual duration because of the heavy nature of the topic discussed. Past research in primary care patients with multi-morbidity has shown that clinician comfort level with these types of difficult

topics is low and that in practicing a traditional "additive-sequential model," where each problem is treated independently and prioritized, these issues may never get acknowledged.[15,30] Therefore, the implementation of ICAN can provide an opportunity to train clinicians to address potentially difficult topics, manage their expectations of those discussions, and learn how to successfully have those conversations. Specifically, this requires attention and clinician exposure in future ICAN trainings to the potentially uncomfortable and off-script conversations that may occur as a result of using the aid, as well as practice in having those conversations first in safe spaces, such as with peers and trainers, prior to real-life clinical encounters.

4.4. Conclusion

In conclusion, we successfully pilot tested the ICAN Discussion Aid in primary care encounters. This study illustrated that ICAN was perceived as feasible to implement in normal clinical practice, did not impact visit length, and impacted the conversation topics discussed in encounters. While patients perceived improved visit success with ICAN use, clinicians perceived worsened visit success. Clinical encounters that were noted as difficult to use ICAN point to additional ICAN training needs in future implementation and study settings. ICAN deserves further testing to determine if its implementation leads to better workload-capacity balance for patients living with chronic illness and if this translates to improved patient health outcomes.

Authors' contributions

KRB was responsible for study design, overall study execution, analysis, and the draft manuscript. CCD and AT conducted videographic analysis and provided critical revisions for the manuscript. MB and RG conducted statistical analysis, created tables, and drafted the statistical sections of the manuscript. EB was responsible for study coordination of the study and data

collection procedures. PO assisted with data cleaning procedures, drafting of the manuscript, and critical revisions to the manuscript. SVA served as clinical champion for the study and provided critical revisions to the manuscript. KS provided revisions to the manuscript and data visualization. VMM assisted KRB with study design and oversight of the project.

Conflicts of Interests

The authors of this manuscript have no conflicts of interests to report.

Funding Statement

This research was supported in part by an internal award from the Mayo Clinic Robert and Arlene Kogod Center for Aging.

Data Availability

All data for this study are published within this manuscript and its supplementary materials. No additional unpublished data is available.

Included Figures

Figure 1: ICAN Discussion Aid

Figure 2: Detailed Enrollment Information

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Table 1: Patient and Encounter Characteristics^				
	ICAN (N=57*)	Pre-Intervention (N=40)	Total (N=97)	p value
Sex				0.09
Female	40 (70.2%)	34 (85.0%)	74 (76.3%)	
Age: Mean (SD)	62.7 (12.0)	66.8 (15.0)	64.4 (13.4)	0.05
Marital status				0.37
Divorced	11 (19.3%)	3 (7.5%)	14 (14.4%)	
Married	36 (63.2%)	27 (67.5%)	63 (64.9%)	
Single	5 (8.8%)	4 (10.0%)	9 (9.3%)	
Widowed	5 (8.8%)	6 (15.0%)	11 (11.3%)	
Length of encounter (minutes): Mean (SD)	31.6 (13.4)	34.5 (11.7)	32.9 (12.7)	0.25
Median (Q1, Q3)	31.3 (19, 41)	34.3 (25, 44)	33.6 (22, 42)	

^All enrolled patients.
*3 patients in intervention missing data on characteristics.

Table 2: CCM Patient Scores

Overall score	ICAN (N=42)	Pre-Intervention (N=39)	Total (N=81)
Mean (SD)	29.7 (11.0)	28.6 (12.4)	29.2(11.6)
Median (Range)	25 (21, 62)	23 (21, 74)	24 (21, 74)
Adjusted mean* (95% CI)	31.5 (24.6, 38.5)	34.6 (29.3, 42.9)	

*Adjusted by clinician clustering; lower scores = better

Table 3: Clinician – Patient Difference in individual CCM scores

	ICAN (N=38)*	Pre-Intervention (n=39)*	P-Value
1/E: Careful to explain	0.87 (0.52, 1.22)	0.64 (0.32, 0.96)	0.33
2/F: Was sympathetic	0.97 (0.57, 1.37)	0.54 (0.19, 0.89)	0.09
3/H: discussed & agreed together what problem was	0.97 (0.61, 1.33)	0.51 (0.19, 0.84)	0.047
4/K: discussed & agreed on plan of treatment	0.84 (0.51, 1.17)	0.59 (0.25, 0.93)	0.26
5/M: understood emotional needs	0.97 (0.43, 1.52)	0.77 (0.39, 1.15)	0.31
6/N: confident knows patient history	0.66 (0.23, 1.09)	0.77 (0.40, 1.14)	0.91
7/T: interested in effect of problem on family and personal life	0.68 (0.22, 1.15)	0.64 (0.27, 1.02)	0.73
8/U: interested in effect of problem on everyday life	0.82 (0.35, 1.29)	0.74 (0.39, 1.10)	0.60
Mean (95% CI), p-value Wilcoxon rank sum test			

* Difference in scores calculated as clinician score minus patient score for encounter. Higher scores correspond to lower performance on the CCM tool.

Table 4: Videographic Analysis of Issues Discussed by Patients and Clinicians

	Behaviors *	All Encounters (n=84/ICAN= 45)		Patients (n=84)		Clinicians (n=84)	
		IRR (95% CI)	P value	IRR (95% CI)	P value	IRR (95% CI)	P value
More likely with ICAN	**Being active**	**1.52 (1.09, 2.11)**	**0.01**	**1.58 (1.12, 2.22)**	**0.008**	1.45 (0.95, 2.21)	0.09
	Taking medications	1.22 (0.99, 1.51)	0.06	**1.42 (1.20, 1.67)**	**<.0001**	1.12 (0.85, 1.46)	0.42
	Diet	**2.02 (1.22, 3.32)**	**0.005**	**2.32 (1.39, 3.88)**	**0.001**	1.61 (0.93, 2.79)	0.09
	Competing priorities	**14.46 (4.00, 52.24)**	**<.0001**	---**	---	**10.91 (3.63, 32.73)**	**<.0001**
Less Likely with ICAN	**Other admin**	**0.56 (0.39, 0.82)**	**0.002**	0.74 (0.48, 1.13)	0.16	**0.47 (0.33, 0.69)**	**<.0001**
	Family	**0.57 (0.36, 0.90)**	**0.02**	0.66 (0.42, 1.03)	0.05	**0.46 (0.28, 0.75)**	**0.002**
	Faith	**0.59 (0.42, 0.82)**	**0.002**	0.78 (0.44, 1.39)	0.41	0.36 (0.12, 1.05)	0.06
	Senses	**0.55 (0.30, 1.00)**	**0.05**	0.65 (0.35, 1.22)	0.18	**0.44 (0.23, 0.87)**	**0.02**
No Difference with ICAN	Other treatment work	0.90 (0.65, 1.24)	0.52	1.07 (0.71, 1.63)	0.74	0.77 (0.59, 1.01)	0.06
	Immediate concerns	1.11 (0.69, 1.76)	0.68	1.62 (0.86, 3.06)	0.14	0.90 (0.60, 1.37)	0.64
	Joy	---**	---	---**	---	---**	---
	Where I live	0.82 (0.50, 1.35)	0.44	1.09 (0.66, 1.80)	0.75	0.58 (0.32, 1.04)	0.07
	Comfort	0.76 (0.50, 1.16)	0.20	0.90 (0.62, 1.33)	0.61	0.63 (0.39, 1.01)	0.05
	Free time	1.08 (0.54, 2.16)	0.82	1.20 (0.60, 2.40)	0.61	0.96 (0.45, 2.04)	0.92
	Making appointments	0.76 (0.50, 1.16)	0.21	0.77 (0.49, 1.23)	0.27	0.75 (0.49, 1.15)	0.18
	Prescribed behaviors	0.84 (0.45, 1.58)	0.59	0.96 (0.57, 1.64)	0.89	0.80 (0.40, 1.61)	0.53
	Friends	0.75 (0.33, 1.66)	0.47	0.65 (0.30, 1.40)	0.27	1.41 (0.52, 3.75)	0.49
	Getting to appointments	1.24 (0.74, 2.08)	0.41	1.34 (0.76, 2.36)	0.32	1.09 (0.60, 2.00)	0.78
	Work	0.85 (0.60, 1.220	0.39	1.05 (0.75, 1.47)	0.80	0.62 (0.38, 1.02)	0.06
	Rest	0.89 (0.52, 1.54)	0.68	0.92 (0.52, 1.59)	0.75	0.87 (0.46, 1.64)	0.67
	Emotional life	1.23 (0.54, 2.80)	0.63	1.56 (0.64, 3.83)	0.33	1.03 (0.41, 2.59)	0.95
	Volunteer	0.85 (0.30, 2.38)	0.76	0.57 (0.16, 2.04)	0.39	---**	---
	Personal meaning	2.39 (0.18, 32.56)	0.51	2.39 (0.18, 31.56)	0.51	---**	---
	School	---**	---	---**	---	---**	---
	Memory	1.98 (0.70, 5.63)	0.20	2.41 (0.71, 8.25)	0.1596	0.80 (0.30, 2.13)	0.65

IRR = Incidence Rate Ratio; >1 means more occurrences in ICAN encounters, <1 fewer occurrences in ICAN encounters
*Adjusted for gender, age at enrollment, length of encounter and clustering around shared clinicians
** Insufficient data for analysis

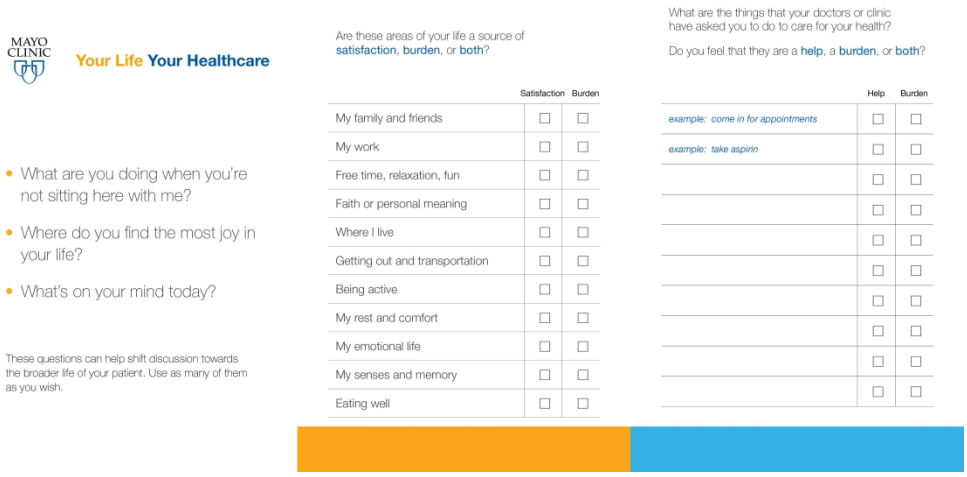

Figure 1: ICAN Discussion Aid

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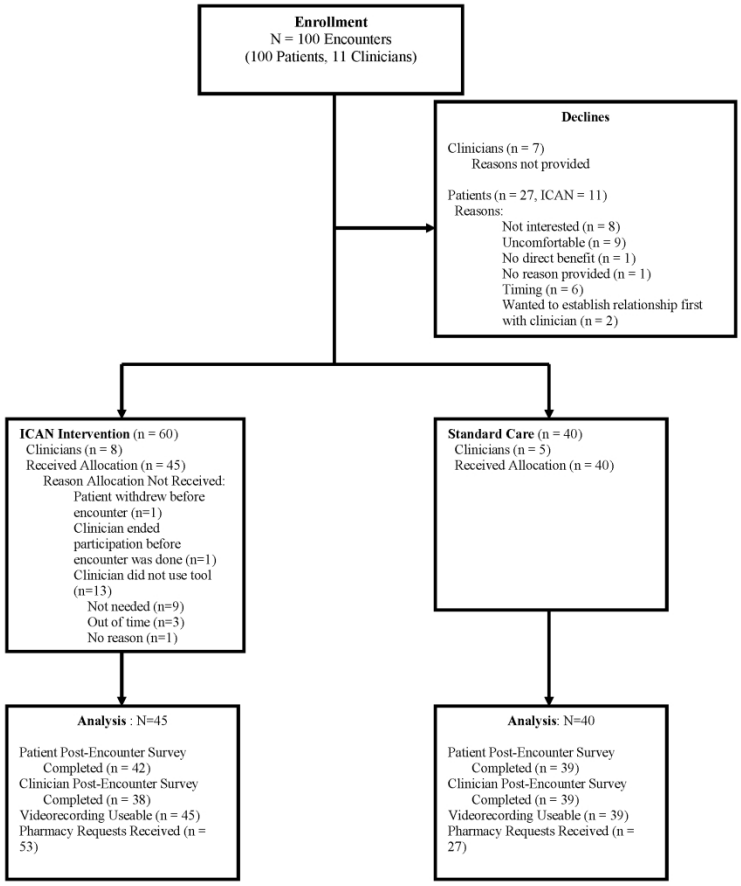

Figure 2: Detailed Enrollment Information

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Appendix 1: Pharmaceutical prescription methods and results

Measure

Patients' prescriptions that had been filled were obtained from their pharmacies directly. We collected information on patients' filled prescriptions six months prior to enrollment to six months post-enrollment. Adherence to treatment was assessed for the six months post-enrollment by calculating the percentage of days out of the 180 day period for which a patient had a filled prescription.[23] Medications to treat chronic conditions were considered for inclusion in analysis.

Appendix Table 1: Included Medications

Medication Class	Medication Name
ACE inhibitor	Enalapril Maleate
	Lisinopril
	Ramipril
Alpha blocker	Tamsulosin
	Tamsulosin HCL
Alpha1 adrenergic blocker	Doxazosin Mesylate
Alpha2 delta ligand	Lyrica
Aminoketone antidepressant	Bupropion
	Bupropion HCL
	Bupropion HCL ER
	Bupropion XL
	SR Bupropion
Angiotensin receptor blocker (ARB)	Candesartan
	Lorsartan Potassium
	Losartan
	Losartan -HCTZ
	Losartan HCTZ
	Losartan Potassium
	Losartan-HCTZ
	Valsartan
Antiandrogen	Bicalutamide
Antiarrhythmic drug	Amiodarone
	Flecainide Acetate

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
Anticoagulant	**Enoxaparin Sodium**
	Jantoven
	Warfarin Sodium
	Xarelto
Anticonvulsant	**Carbamazepine**
	Carbamazepine ER
	Gabapentin
	Lamotrigine
	Topiramate
	Zonisamide
Anxiolytic antianxiety agent	**Buspirone**
Atypical antipsychotic	**Latuda**
	Quetiapine
	Quetiapine Fumarate
Beta blocker	**Atendlol Chlorthalidone**
	Atenolol
	Bisoprolol
	Carvedilol
	ER Metoprolol
	Metoprolol ER
	Metoprolol ER Succinate
	Metoprolol SUCC ER
	Metoprolol Tart
	Metoprolol Tartrate
	Metoprololhydrochloroth
	Timolol Maleate
Biguanide	**Metforman**
	Metformin
	Metformin ER
	Metformin HCL

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
	Metformin HCL ER
	metformin
Bisphosphonate	**Alendronate**
	Alendronate Sodium
Calcium channel blocker	**Amlodipine**
	Amlodipine Besylate
	Diltiazem HCL ER
	Nifedipine
	Verapamil HCR ER
Central alpha agonist	**Clonidine HCL**
Central muscle relaxant	**Methocarbamol**
Class 1b antiarrhythmic drug	**Lidocaine**
DDP4 inhibitor + biguanide	**Janumet XR**
Dibenzazepine	**Tegretol XR**
Digitalis glycoside	**Digoxin**
Disease modifying antirheumatic drug (DMARD)	**Hydroxychloroquine Sulfate**
Diuretic	**Hydrochilorothiazide**
	Hydrochlorothiazide
	Metolazone
Fibric acid	**Fenofibrate**
	Fenofibrate Micronized
Janus kinase (JAK) inhibitors	**Xeljanz**
Leukotriene receptor antagonists	**Montelukast Sodium**
Loop diuretic	**Furobemide**
	Furosemide
	Torsemide
Nitrate	**Isosorb Mono ER**
	Isosorbide MN ER
Nonergoline dopamine agonist	**Pramipexole**
Oral diuretic	**Triamterene-HCTZ**

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
P2Y12 inhibitor	**Clopidogrel**
	Clopidogrel Bisulfate
Phenylpiperazine antidepressant	**Nefazodone HCL**
Phosphodiesterase 4 (PDE4) inhibitors	**Otezla**
Potassium sparing diuretic	**Spironolactone**
SNRI	**Desvenlafaxine ER**
	Duloxetine DR
	Duloxetine HCL
	Duloxetine Hcl
	ER Venlafaxine
	Escitalopram Oxalate
	Venafaxine XR
	Venlafaxin XR
	Venlafaxine ER
	Venlafaxine HCL ER
	Venlafaxine XR
SSRI	**Citalopram**
	Citalpram
	Fluoxetine
	Fluoxetine HCL
	Paroxetine
	Paroxetine HCL
	Sertraline
	Sertraline HCL
Selective estrogen receptor modulator (SERM)	**Raloxifene HCL**
	Tamoxifen
Statin	**Atorvastatin**
	Atorvastatin Calcium
	Locastatin
	Lovastatin

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
	Pravastatin Sodium
	Rosuvastatin Calcium
	Simvastatin
	Vytorin
Sulfonylurea	**Climepiride**
	Glimepiride
	Glipizide
	Glipizide ER
	Glipizide XL
Tetracyclic antidepressant	**Mirtazapine**
Thiazide diuretic	**Chlorthalidone**
Thyroxine; T4 (synthetic)	**Levothroxine**
	Levothyroxine
	Levothyroxine SOD
	Synthroid
Triazolopyridine antidepressant	**Trazodone HCL**
Tricyclic antidepressant	**Amitriptyline HCL**
	Cyclobenzaprine HCL
	Cyclovbenzaprine HCL
	Cyclovenzaprine HCL
	Nortiptyline
	Nortriptyline
	Nortriptyline HCL
Triiodothyronine	**Liothyronine Sodium**
Valeric acid	**Gemfibrozil**
Missing	**Missing**
Other / Unknown	**Amsulosin**
	Isometh-apap-dichlor-
	Metromin HCL
	Oxycodone 5MG IR Tabs

Statistical Analysis

Adherence to medications was assessed by medication class (i.e. if patient had multiple medications within a class, average adherence was calculated). Adherence was modeled using a hierarchical generalized linear model where the outcome was a patients' medication class adherence six months post enrollment. The model was clustered by patient, as patients could have multiple classes of medication, and adjusted by their adherence to the medication class in the six months prior to enrollment and intervention arm. Patients who did not have the medication class in the prior period were set to zero for baseline and a missing indicator was assessed in the model to address this. Patients with missing pharmacy data (e.g. their pharmacy

Adherence Results

Similar rates of medication counts, medication classes and adherence were seen between groups in the six months prior to the encounter of interest (76% of days covered in patients in the ICAN group vs. 71% control)was unreachable for data request) were not included in the analysis.

Appendix Table 2: Analysis of percent of days covered of medication classes by intervention.

	ICAN (N=53)	Pre-Intervention (N=27)	p value
Count of medications prior to encounter			0.57
Mean (SD)	3.6 (2.6)	4.2 (3.3)	
Median (IQR)	3 (2, 5)	4 (2, 5)	
Count of medication classes prior to encounter			0.54
Mean (SD)	3.4 (2.3)	3.9 (2.9)	
Median	3 (1, 5)	4 (2, 5)	
Adherence (PDC) prior to encounter			0.94
Mean (95% CI)	55% (50, 60)	54% (50, 60)	
Count of medications post encounter			0.37
Mean (SD)	3.8 (2.5)	4.1 (2.0)	
Median	3 (2, 5)	4 (3, 5)	
Count of medication classes post encounter			0.36
Mean (SD)	3.6 (2.3)	3.9 (1.8)	
Median	3 (2, 5)	4 (3, 5)	

Appendix Table 2: Analysis of percent of days covered of medication classes by intervention.			
	ICAN (N=53)	Pre-Intervention (N=27)	p value
Adherence (PDC) post encounter			0.56
Mean (95% CI)	75% (70, 80)	71% (60, 80)	
Adjusted adherence (PDC) post encounter^			0.43
Mean (95% CI)	76% (70, 80)	72% (60, 80)	

Acronym: PDC Percent of Days Covered

* Prior and post encounter periods are each 6 months long.

^ ANCOVA with random effect of clinician and adjusted by prior 6 months adherence and intervention.

BMJ Open

Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and Feasibility Study of the ICAN Discussion Aid

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-029105.R2
Article Type:	Research
Date Submitted by the Author:	12-Jul-2019
Complete List of Authors:	Boehmer, Kasey R.; Mayo Clin, Dobler, Claudia; Mayo Clin, Knowledge and Evaluation Research Unit; 2. Evidence-Based Practice Center, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery Thota, Anjali; Mayo Clin, Knowledge and Evaluation Research Unit Branda, Megan; Mayo Clinic, Health Sciences Research Giblon, Rachel; Mayo Clin, 3. Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery Behnken, Emma; Mayo Clin, Knowledge and Evaluation Research Unit Organick, Paige; Mayo Clin, Knowledge and Evaluation Research Unit Allen, Summer; Mayo Clin, Knowledge and Evaluation Research Unit; Department of Family Medicine Shaw, Kevin; Mayo Clin, Knowledge and Evaluation Research Unit Montori, Victor; Mayo Clinic, Knowledge and Encounter Research Unit
Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Communication
Keywords:	patient-centered care, minimally disruptive medicine, healthcare communication, chronic disease, multimorbidity

Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and Feasibility Study of the ICAN Discussion Aid

Kasey R. Boehmer, PhD, MPH[1] (Boehmer.kasey@mayo.edu)
Claudia C. Dobler, MD, PhD[1,2] (Dobler.claudia@mayo.edu)
Anjali Thota, BA[1] (Thota.anjali@mayo.edu)
Megan Branda, MS[3] (Branda.megan@mayo.edu)
Rachel Giblon, MS[3] (Giblon.rachel@mayo.edu)
Emma Behnken, BA[1] (Behnken.emma@mayo.edu)
Paige Organick, BA[1] (Organick.paige@mayo.edu)
Summer V. Allen, MD[1,4] (Allen.summer@mayo.edu)
Kevin Shaw, BA[1] (Shaw.kevin@mayo.edu)
Victor M. Montori, MD, MSc[1] (Montori.victor@mayo.edu)

1. Knowledge and Evaluation Research Unit, Mayo Clinic, Rochester, Minnesota, USA
2. Evidence-Based Practice Center, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, USA
3. Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota, USA
4. Department of Family Medicine, Mayo Clinic, Rochester, Minnesota

Corresponding Author:
Kasey R. Boehmer, PhD, MPH
Mayo Clinic
200 First Street SW
Rochester, MN 55905

Support: Funded by an internal Mayo Clinic Award from the Robert & Arlene Kogod Center for Aging; This publication was supported by CTSA Grant Number UL1 TR002377 from the National Center for Advancing Translational Science (NCATS). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.

Prior Presentations: International Shared Decision Making Conference, Lyon, France, 2017; International Conference on Communication in Healthcare, Baltimore, MD, USA, 2017; North American Primary Care Research Group Conference, Montreal, Canada, 2017

Word Count: 3,532; 2 Figures, 4 Tables, 1 Appendix

Abstract

Purpose: To pilot test the impact of the ICAN Discussion Aid on clinical encounters.

Methods: A pre-post study involving 11 clinicians and 100 patients was conducted at two primary care clinics within a single health system in the Midwest. The study examined clinicians' perceptions about ICAN feasibility, patients' and clinicians' perceptions about encounter success, videographic differences in encounter topics, and medication adherence 6-months after an ICAN encounter.

Results: 39/40 control encounters and 45/60 ICAN encounters yielded usable data. Clinicians reported ICAN use was feasible. In ICAN encounters, patients discussed diet, being active, and taking medications more. Clinicians scored themselves poorer regarding visit success than their patients scored them; this effect was more pronounced in ICAN encounters. ICAN did not improve 6-month medication adherence or lengthen visits.

Conclusion: This pilot study suggests that using ICAN in primary care is feasible, efficient, and capable of modifying conversations. With lessons learned in this pilot, we are conducting a randomized trial of ICAN vs. usual care in diverse clinical settings.

Abstract Word Count: 166

Keywords: patient-centered care; minimally disruptive medicine; healthcare communication; chronic disease; multimorbidity

Trial Registration: NCT02390570; registered 2/19/2015

Article Summary: Strengths and limitations of this study

- Small before-after pilot study limiting the ability to draw statistical inferences that would be possible in a larger trial with a randomized design.
- Not powered to assess clinical significance for patient-reported outcomes nor prescription adherence; lack of difference found is not indicative of one not existing
- Single healthcare system in the Midwest with a fairly homogenous patient population limiting generalizability
- Small size was a strength in allowing us to pursue video-recording of all encounters, allowing deeper exploration of ICAN's impact on conversations and additional training needs for future implementation and testing

1. Introduction

Estimates in 2013 indicated that 117 million, or approximately half of adults in the U.S. had one or more chronic conditions,[1] while 26% of adults in the U.S. had multiple chronic conditions (MCC).[2] Patients living with chronic conditions must cope with the burden of illness and additionally invest time and energy to comprehend, manage, and access professional healthcare – the work of being a patient. If this work is not carefully managed and monitored, patients may experience treatment burden.[3,4]

Treatment burden often goes unnoticed, as clinical practice guidelines focus on managing individual conditions, without explicit consideration of co-morbidities or the patient's values, preferences, and context.[5] If implemented in this way, the application of all guideline recommendations may overwhelm patients [6-8]. Similarly, clinical practice does not often acknowledge patients' potentially limited capacity to handle complexity of life and healthcare work, which leads to the prescription of treatment plans that require capacity of patients and their caregivers that they may not have.[9,10]

This situation not only impacts patients and families, but has also led to burnt-out clinicians.[11] Beyond medical complexity described above, clinicians also need to consider non-medical complexity, (e.g., difficulty affording medications, unstable housing, and problematic family dynamics), and the body of literature is growing to show that clinicians have difficulty with conversations where medical and non-medical complexity intersect. [12-16]

The ICAN Discussion Aid (**Figure 1**) was developed to address these problems, with the aim of enabling the discussion of patient workload, capacity, and treatment burden within the time constraints of busy primary care visits.[17] The process to develop ICAN is described in full elsewhere.[17] Briefly, it was developed using a robust, iterative user-centered design process,

previously used to develop decision aids[18] and was grounded in the Cumulative Complexity Model, which states that patients living with chronic illness must enact both patient and life work with limited capacity.[19] When workload exceeds patient capacity, it affects patients' abilities to access and use healthcare and enact self-care, in turn effecting their health outcomes.[19] In addition to worsening health outcomes, unaddressed workload-capacity imbalance can lead to a vicious cycle of added treatment burden and illness burden.[19]

To date, the ICAN Discussion Aid remains untested in terms of its impact on the discussion of patient workload, capacity, and treatment burden in the clinical encounter. We hypothesize that if ICAN proves feasible in busy primary care and positively impacts the clinical encounter with greater discussion of patients' context, it could spark treatment plans that better fit patients' lives, with downstream impact on patient health outcomes and quality of life.

1.2. Aim

We aimed to evaluate the feasibility of using the ICAN Discussion Aid in primary care and to estimate its impact on clinical care, including patient and clinician-perceived success of visits, length of visits, and topics of conversation.

2. Methods

To pilot test the ICAN Discussion Aid, we conducted a pre-test versus post-test intervention study.

2.1. Ethics

All study procedures were approved by the Mayo Clinic IRB (14-008621); patient and clinician participants consented for data collection procedures.

2.2. Participant Eligibility and Recruitment

Clinicians were recruited from two clinical sites in the Midwest and were eligible for participation if they regularly saw patients with chronic conditions. Clinicians were consented for participation either at a lunch-hour clinical practice meeting or immediately before their first eligible patient. Clinicians were consented by the principal investigator (KRB) or a trained study coordinator. Adult patients were eligible if they had one or more chronic conditions, no major barriers to consent (e.g. cognitive impairment), and were seeing a clinician who had agreed to participate. To assess for barriers to consent, we used the electronic medical record to look for keywords such as language, cognitive function, serious vision/hearing impairment, etc., and also confirmed with the primary care clinician that the patients did not have any of the listed barriers to consent and were appropriate to include in the study. Patients were approached immediately before the encounter with their clinician by a trained study coordinator.

2.3 Study Procedures

After both clinician and patient were enrolled in the study, a trained study coordinator set up a small video camera (i.e., FlipCam, GoPro) to record the clinic visit. Patients and clinicians could turn the video camera off at any time if they felt uncomfortable, and the video camera was always turned around or off during physical exams. Following the encounter, both patient and clinician were given a survey to complete immediately or return in a postage-paid return envelope. The study coordinator followed-up on surveys not returned within one week. The first 40 clinical encounters were usual care. After the first 40 encounters, clinicians were then trained during a standing meeting or individually on how to use the ICAN Discussion Aid. The remaining 60 clinical encounters were intended to be ICAN encounters.

2.4. Intervention: The ICAN Discussion Aid

The study coordinator provided instructions for the patient to complete the ICAN Discussion Aid (**Figure 1)** before the clinician entered the room. When the clinician entered the room, he or she would select one of three opening questions to elicit responses from the patient, and would then explore the information that the patient provided in ICAN by asking "What stands out to you on this sheet you filled?" Clinicians were instructed to discuss that issue alone and connect it to the reason for the visit that day. Clinical conversation was expected to proceed as usual with incorporation of the ICAN information.

2.5. Measures

Clinician degree, position, and gender were collected at baseline. Patient characteristics of age, sex and marital status were abstracted from the medical record. To assess *perceived success* of the encounter, we used the Consultation Care Measure (CCM), a valid and discriminating tool to measure communication and partnership within a single encounter, previously correlated with patient satisfaction, enablement, and reduced symptom burden.[20] The measure asks patients to what extent they agree with statements about the doctor such as he/she "was interested in what I thought the problem was."[20] For clinician surveys, we used a modified version of the patient CCM, adjusted to the clinician perspective, which was not previously validated. For example, the patient might be asked the extent to which they felt the clinician "was careful to explain the plan of treatment." Whereas the clinician would be asked the extent to which they agreed with the statement that they felt that they "were careful to explain the plan of treatment." To assess *feasibility* of ICAN use, we asked clinicians to report how easy or difficult the aid was to use in their encounter on a 5-point scale, from very easy to very difficult. If clinicians marked difficult or very difficult, they were prompted to write a brief description of

why. To assess *adherence, p*atients pharmaceutical records were collected as a means to provide estimates of baseline adherence amongst patients in this population, and of whether using ICAN potentially effects adherence through the tailoring of patient care plans to their life context. Given the hypothesis generating nature of the adherence data, the methods and results are provided in **Appendix 1.**

2.6. Videographic Coding Scheme

To assess ICAN's *impact on clinical conversation topics*, we created an a priori video coding scheme, in which we coded each instance where the following topics were brought up: family, friends, free time, faith, living situation, being active, rest, comfort, emotional life, senses, memory, eating well, taking medications, making appointments, getting to appointments, administrative treatment work (e.g., dealing with insurance/billing, communicating with pharmacies), prescribed behaviors (e.g. getting mammograms, exercising a certain number of minutes per week), and other treatment work (i.e, work that the patient was asked to do but that did not fit into these other categories). Life issues listed in the coding scheme were those shown on ICAN and previously illustrated as important components of patient capacity from earlier work.[17,21] Treatment burden issues listed in the coding scheme were derived from typical issues listed in the development of ICAN and a taxonomy of treatment burden.[17,22] We also coded for opening questions typically used in ICAN, designed to elicit the existence of competing priorities that could potentially limit the capacity for self-care or treatment, sources of joy in patients' lives, and immediate concerns (medical and non-medical). To assess *impact on length of visit*, we compared lengths of video recording.

2.7. Analyses

All statistical analyses were conducted in SAS (SAS Institute Inc., Version9.4, Cary, NC, USA) and Stata (StataCorp, Release 15. College Station, TX). Videographic coding was done using Noldus Observer XT (version 11, Leesburg, VA). Patient and clinical encounter characteristics were compared between ICAN and control encounters using a t-test for continuous variables and a chi-square test for categorical variables. To explore differences in patient and clinician perceived success of an encounter, we subtracted unadjusted clinician scores from unadjusted patient scores, and tested for changes in the perceived success gap between ICAN and control encounters using a Wilcoxson Rank-Sum test. To test for differences across issues discussed in videos where patients and clinicians used ICAN versus those recorded in control encounters, we used a negative binomial model accounting for clustering within clinicians.

2.8 Patient and Public Involvement

The Knowledge and Evaluation Research Unit Patient Advisory Group participated in the design of the ICAN Discussion Aid, ensuring its relevance to patients living with chronic conditions and its ease of use. They were not consulted for the research design of the pilot study.

3. Results

Eleven clinicians were enrolled from two primary care clinics within the Midwest, United States starting in October 2015. Seven clinicians approached declined enrollment, without providing a reason. The clinicians were primarily female (N=7, 64%) and were primarily physicians, with one nurse practitioner and two physician assistants. Patient enrollment began October 2015 and ended February 2017. 100 patients consented to participate (ICAN n=60). Detailed enrollment information is depicted in **Figure 2**. Of the eleven clinicians participating,

one had all control encounters and five had all ICAN encounters. Patient characteristics are depicted in **Table 1**. Encounter length did not significantly differ between ICAN and control encounters.

3.1. Clinician reported feasibility of ICAN

Clinicians found the tool feasible to use in the majority of encounters. 62% reported it very easy or easy, 32% reported it as neither easy nor difficult, and 5% reported it was difficult to use in that encounter. There were two encounters where it was reported as difficult by different clinicians. For one encounter the clinician stated, "Unfortunately, this made her appointment go over by about 30 minutes. It was good we discussed issues with the portal [*an online platform that allows patients to access their health information*] and her life and stressors but it wasn't a big concern (why it wasn't a reason for the appointment) but we spent a good deal of time on it." Upon further review of this video, it appears that the primary reason that the encounter lasted substantially longer than planned was a lack of fidelity to ICAN training. After the clinician asked the patient what stood out to her from ICAN, she continued to elicit information about each burden listed by the patient, rather than connect the patient's response to the remainder of the clinical visit. Addressing the two key issues the patient brought up, work stress and being active, took approximately five and a half minutes in total. Following that, the clinician spent an additional five and a half minutes reviewing the other items on the tool.

In the second encounter, the clinician stated, "I enjoy the learning and conversation obtained from form [*sic*] but didn't have the extra time in schedule [*sic*] necessary to address each issue - easily added another 15-20 minutes to appointment." In this encounter, the patient indicated that her emotional life was both a source of satisfaction and a burden. The clinician enquired further and thus provided the patient with an opportunity to talk about her prolonged

grief after the loss of her spouse and her concerns about possible depression. In response the clinician screened the patient for potential depression. Total time using the tool and discussing that issue took four minutes of the total visit. The patient was scheduled for a 45 minute general medical exam, and the total video recorded visit time was 26 minutes, which did not include the physical exam at the end of the encounter.

3.2. Survey Results

We did not find any items with significant differences between patients in either cohort for the consultation care measure (**Table 2**). When comparing patients and clinicians across the consultation care measure, among the items that overlapped, clinicians tended to score themselves poorer than patients. This was more prevalent when the ICAN tool was used (**Table 3**).

3.3. Videographic Results

Issues discussed during clinical encounters did significantly differ between ICAN and control encounters in multiple domains (**Table 4**). Specifically, discussions about being active, diet, and taking medications were discussed significantly more frequently in ICAN encounters. Discussions about administrative treatment work, other treatment work, family, living arrangements, and comfort were discussed significantly less frequently in ICAN encounters. We noticed that often topics about family were used as conversation fillers in control encounters, whereas there may have been less room for this when patients were prompted to bring up issues that mattered most to them.

4. Discussion and Conclusion

4.1. Summary of Findings

Within this pilot trial, clinicians found the ICAN Discussion Aid to be a tool they could feasibly adopt into everyday practice and which did not impact the length of the visit. Patients discussed diet, being active, and taking medications more often in ICAN encounters. Additionally, clinicians elicited competing priorities using ICAN opening questions that were never elicited during the opening of control encounters. While clinicians rated the perceived success of their encounters poorer than their patients (CCM score), and the gap between patient and clinician perceived success was larger ICAN encounters, the difference was not significant. No difference was seen for adherence to prescription medications.

4.2. Limitations and Strengths

These findings cannot be interpreted without considering the limitations in this study design. First, this study was a small before-after pilot study which limits our ability to draw statistical inferences that would be possible in a larger trial with a randomized design. The study was not powered to assess clinical significance for patient-reported outcomes nor prescription adherence and a lack of difference found is not indicative of one not existing. Furthermore, the study occurred within a single healthcare system in the Midwest with a fairly homogenous patient population of mostly high or middle socioeconomic status, which limits the generalizability of the specific changes in topics present in ICAN conversations versus usual care conversations. However, the small size of the study allowed us to pursue video-recording of all encounters, which allowed for deeper exploration of ICAN's impact on conversations and to point to additional needs for future implementation and testing of ICAN in practice that would have been more difficult in a larger multi-site study.

4.3 Missing Data

Detailed missing data information is depicted in **Figure 2** and should be considered when interpreting the study's findings**.** 39/40 baseline encounters yielded usable data. One survey was unreturned and one encounter's videographic coding was lost due to technical error. 45/60 follow-up encounters yielded usable data. 15 videos during the intervention period were excluded from analyses because although the clinician had been trained in using ICAN and intended to use it in the encounter, they did not use the tool during the encounter. This occurred for a variety of reasons including that the patient brought up more pressing concerns for that day that made the clinician feel the ICAN tool was no longer appropriate for that encounter or the clinician simply forgot to use the tool. Consent to pharmacy record review was an optional portion of the study, therefore reducing the number of profiles available. For all patients that consented to this optional portion, pharmacy records were requested. However, in some cases, the pharmacy did not return a profile for the patient after two request attempts, whereas in other cases, the patient did not have any active prescriptions at the pharmacy on file for chronic conditions.

4.4. Practice Implications

Feasibility of ICAN use is an important finding on its own, given previously reported challenges by clinicians in providing patient-centered care and participating in shared decision making for populations living with MCC.[23] Furthermore, the difference in the topics brought up in ICAN encounters suggests that patients are indeed more likely to be able to voice their topics of choice, in an area where poor communication has been a noted frustration amongst patients.[24] Diet, being active, and taking medications are not surprising topics to be most important to

patients in this setting and population (suburban, Midwest, academic medical center). However, these topics have been noted as important treatment burden factors for patients in other diverse samples; patients noted that they were aware their clinicians wanted them to eat healthier or exercise more frequently, but important barriers existed of which their clinicians were unaware.[25] Furthermore, in a previous study of patient-clinician concordance, patients were more likely than clinicians to rank being active as one of their top three health concerns.[26] Future research should examine whether the topics discussed more often are different in other clinical settings (e.g. rural and urban), with different populations (e.g. unsalaried clinicians, underserved patients), and what clinicians can do in clinical encounters with this information.

Ultimately, the discussion of topics of greater importance to patients and their competing priorities is important as it could lead to better tailoring of treatment plans to patients' context, improving patients' workload-capacity balance in managing chronic illness. As mentioned earlier, the Cumulative Complexity Model postulates that workload-capacity balance impacts patients' abilities to access and use healthcare and enact self-care, with downstream impact on their health outcomes.[19] Furthermore, communication models, such as the one proposed by Street et al. have postulated the pathways from patient-clinician communication to patient outcomes.[27] For example, Street's model illustrates that communication functions supported by ICAN such as managing uncertainty, fostering relationships, and enabling self-management can impact proximal outcomes such as patient trust and "feeling known," with downstream consequences on self-care skills, adherence, and ultimately health outcomes.[27] ICAN is a general discussion aid for use in chronic illness, intended to provide insight into the personal, social, material, and spiritual aspects of the patient's situation; it can be used in conjunction with the many available decision-specific conversation aids.[28] For example, an ICAN conversation may illuminate that a

patient finds their overall medication regimen particularly burdensome, and this may spark a treatment-specific conversation about choosing a different treatment in replacement of a current one or inform the decision to add or not add another medication to the list. A good example of the use of ICAN and a treatment decision aid is available on the web.[29] Used in this way, clinicians may fully understand patients' competing priorities as well as treatment-specific values and preferences, and therefore, be able to co-create with them treatment plans that fit their context and allow them to lead quality lives to the fullest extent.

Examining the two encounters noted as difficult for clinicians yielded important information about ICAN implementation challenges. The encounter where additional time was used to discuss all ICAN items suggests that additional training may be needed for clinicians to illustrate how to connect the initial question of "What stands out to you?" to the clinical reason for the appointment, and how to continue the use of the discussion aid at future encounters. In the encounter in which the patient was able to discuss potential concerns of depression, the clinician noted that this added an additional 15 – 20 minutes to the encounter, whereas the actual discussion took less than five minutes. The perceived duration may have felt longer than the actual duration because of the heavy nature of the topic discussed. Past research in primary care patients with multi-morbidity has shown that clinician comfort level with these types of difficult topics is low and that in practicing a traditional "additive-sequential model," where each problem is treated independently and prioritized, these issues may never get acknowledged.[15,30] Therefore, the implementation of ICAN can provide an opportunity to train clinicians to address potentially difficult topics, manage their expectations of those discussions, and learn how to successfully have those conversations. Specifically, this requires attention and clinician exposure in future ICAN trainings to the potentially uncomfortable and off-script conversations that may occur as a

result of using the aid, as well as practice in having those conversations first in safe spaces, such as with peers and trainers, prior to real-life clinical encounters.

4.5. Conclusion

In conclusion, we successfully pilot tested the ICAN Discussion Aid in primary care encounters. This study illustrated that ICAN was perceived as feasible to implement in normal clinical practice, did not impact visit length, and impacted the conversation topics discussed in encounters. While patients perceived improved visit success with ICAN use, clinicians perceived worsened visit success. Clinical encounters that were noted as difficult to use ICAN point to additional ICAN training needs in future implementation and study settings. ICAN deserves further testing to determine if its implementation leads to better workload-capacity balance for patients living with chronic illness and if this translates to improved patient health outcomes.

Authors' contributions

KRB was responsible for study design, overall study execution, analysis, and the draft manuscript. CCD and AT conducted videographic analysis and provided critical revisions for the manuscript. MB and RG conducted statistical analysis, created tables, and drafted the statistical sections of the manuscript. EB was responsible for study coordination of the study and data collection procedures. PO assisted with data cleaning procedures, drafting of the manuscript, and critical revisions to the manuscript. SVA served as clinical champion for the study and provided critical revisions to the manuscript. KS provided revisions to the manuscript and data visualization. VMM assisted KRB with study design and oversight of the project.

Conflicts of Interests

The authors of this manuscript have no conflicts of interests to report.

Funding Statement

This research was supported in part by an internal award from the Mayo Clinic Robert and Arlene Kogod Center for Aging.

Data Availability

Patients in this study provided informed consent regarding the use of their de-identified data beyond the proposed study. De-identified data from participants that consented to future use of their data is available upon request from investigators in the Knowledge and Evaluation Research Unit.

Included Figures

Figure 1: ICAN Discussion Aid

Figure 2: Detailed Enrollment Information

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Table 1: Patient and Encounter Characteristics^				
	ICAN (N=57*)	Pre-Intervention (N=40)	Total (N=97)	p value
Sex				0.09
Female	40 (70.2%)	34 (85.0%)	74 (76.3%)	
Age: Mean (SD)	62.7 (12.0)	66.8 (15.0)	64.4 (13.4)	0.05
Marital status				0.37
Divorced	11 (19.3%)	3 (7.5%)	14 (14.4%)	
Married	36 (63.2%)	27 (67.5%)	63 (64.9%)	
Single	5 (8.8%)	4 (10.0%)	9 (9.3%)	
Widowed	5 (8.8%)	6 (15.0%)	11 (11.3%)	
Length of encounter (minutes): Mean (SD)	31.6 (13.4)	34.5 (11.7)	32.9 (12.7)	0.25
Median (Q1, Q3)	31.3 (19, 41)	34.3 (25, 44)	33.6 (22, 42)	

^All enrolled patients.
*3 patients in intervention missing data on characteristics.

Table 2: CCM Patient Scores

Overall score	ICAN (N=42)	Pre-Intervention (N=39)	Total (N=81)
Mean (SD)	29.7 (11.0)	28.6 (12.4)	29.2(11.6)
Median (Range)	25 (21, 62)	23 (21, 74)	24 (21, 74)
Adjusted mean* (95% CI)	31.5 (24.6, 38.5)	34.6 (29.3, 42.9)	

*Adjusted by clinician clustering; lower scores = better

Table 3: Clinician – Patient Difference in individual CCM scores

	ICAN (N=38)*	Pre-Intervention (n=39)*	P-Value
1/E: Careful to explain	0.87 (0.52, 1.22)	0.64 (0.32, 0.96)	0.33
2/F: Was sympathetic	0.97 (0.57, 1.37)	0.54 (0.19, 0.89)	0.09
3/H: discussed & agreed together what problem was	0.97 (0.61, 1.33)	0.51 (0.19, 0.84)	0.047
4/K: discussed & agreed on plan of treatment	0.84 (0.51, 1.17)	0.59 (0.25, 0.93)	0.26
5/M: understood emotional needs	0.97 (0.43, 1.52)	0.77 (0.39, 1.15)	0.31
6/N: confident knows patient history	0.66 (0.23, 1.09)	0.77 (0.40, 1.14)	0.91
7/T: interested in effect of problem on family and personal life	0.68 (0.22, 1.15)	0.64 (0.27, 1.02)	0.73
8/U: interested in effect of problem on everyday life	0.82 (0.35, 1.29)	0.74 (0.39, 1.10)	0.60

Mean (95% CI), p-value Wilcoxon rank sum test

* Difference in scores calculated as clinician score minus patient score for encounter. Higher scores correspond to lower performance on the CCM tool.

Table 4: Videographic Analysis of Issues Discussed by Patients and Clinicians

	Behaviors *	All Encounters (n=84/ICAN= 45)		Patients (n=84)		Clinicians (n=84)	
		IRR (95% CI)	P value	IRR (95% CI)	P value	IRR (95% CI)	P value
More likely with ICAN	**Being active**	**1.52 (1.09, 2.11)**	**0.01**	**1.58 (1.12, 2.22)**	**0.008**	1.45 (0.95, 2.21)	0.09
	Taking medications	1.22 (0.99, 1.51)	0.06	**1.42 (1.20, 1.67)**	**<.0001**	1.12 (0.85, 1.46)	0.42
	Diet	**2.02 (1.22, 3.32)**	**0.005**	**2.32 (1.39, 3.88)**	**0.001**	1.61 (0.93, 2.79)	0.09
	Competing priorities	**14.46 (4.00, 52.24)**	**<.0001**	---**	---	**10.91 (3.63, 32.73)**	**<.0001**
Less Likely with ICAN	**Other admin**	**0.56 (0.39, 0.82)**	**0.002**	0.74 (0.48, 1.13)	0.16	**0.47 (0.33, 0.69)**	**<.0001**
	Family	**0.57 (0.36, 0.90)**	**0.02**	0.66 (0.42, 1.03)	0.05	**0.46 (0.28, 0.75)**	**0.002**
	Faith	**0.59 (0.42, 0.82)**	**0.002**	0.78 (0.44, 1.39)	0.41	0.36 (0.12, 1.05)	0.06
	Senses	**0.55 (0.30, 1.00)**	**0.05**	0.65 (0.35, 1.22)	0.18	**0.44 (0.23, 0.87)**	**0.02**
No Difference with ICAN	Other treatment work	0.90 (0.65, 1.24)	0.52	1.07 (0.71, 1.63)	0.74	0.77 (0.59, 1.01)	0.06
	Immediate concerns	1.11 (0.69, 1.76)	0.68	1.62 (0.86, 3.06)	0.14	0.90 (0.60, 1.37)	0.64
	Joy	---**	---	---**	---	---**	---
	Where I live	0.82 (0.50, 1.35)	0.44	1.09 (0.66, 1.80)	0.75	0.58 (0.32, 1.04)	0.07
	Comfort	0.76 (0.50, 1.16)	0.20	0.90 (0.62, 1.33)	0.61	0.63 (0.39, 1.01)	0.05
	Free time	1.08 (0.54, 2.16)	0.82	1.20 (0.60, 2.40)	0.61	0.96 (0.45, 2.04)	0.92
	Making appointments	0.76 (0.50, 1.16)	0.21	0.77 (0.49, 1.23)	0.27	0.75 (0.49, 1.15)	0.18
	Prescribed behaviors	0.84 (0.45, 1.58)	0.59	0.96 (0.57, 1.64)	0.89	0.80 (0.40, 1.61)	0.53
	Friends	0.75 (0.33, 1.66)	0.47	0.65 (0.30, 1.40)	0.27	1.41 (0.52, 3.75)	0.49
	Getting to appointments	1.24 (0.74, 2.08)	0.41	1.34 (0.76, 2.36)	0.32	1.09 (0.60, 2.00)	0.78
	Work	0.85 (0.60, 1.220	0.39	1.05 (0.75, 1.47)	0.80	0.62 (0.38, 1.02)	0.06
	Rest	0.89 (0.52, 1.54)	0.68	0.92 (0.52, 1.59)	0.75	0.87 (0.46, 1.64)	0.67
	Emotional life	1.23 (0.54, 2.80)	0.63	1.56 (0.64, 3.83)	0.33	1.03 (0.41, 2.59)	0.95
	Volunteer	0.85 (0.30, 2.38)	0.76	0.57 (0.16, 2.04)	0.39	---**	---
	Personal meaning	2.39 (0.18, 32.56)	0.51	2.39 (0.18, 31.56)	0.51	---**	---
	School	---**	---	---**	---	---**	---
	Memory	1.98 (0.70, 5.63)	0.20	2.41 (0.71, 8.25)	0.1596	0.80 (0.30, 2.13)	0.65

IRR = Incidence Rate Ratio; >1 means more occurrences in ICAN encounters, <1 fewer occurrences in ICAN encounters

*Adjusted for gender, age at enrollment, length of encounter and clustering around shared clinicians

** Insufficient data for analysis

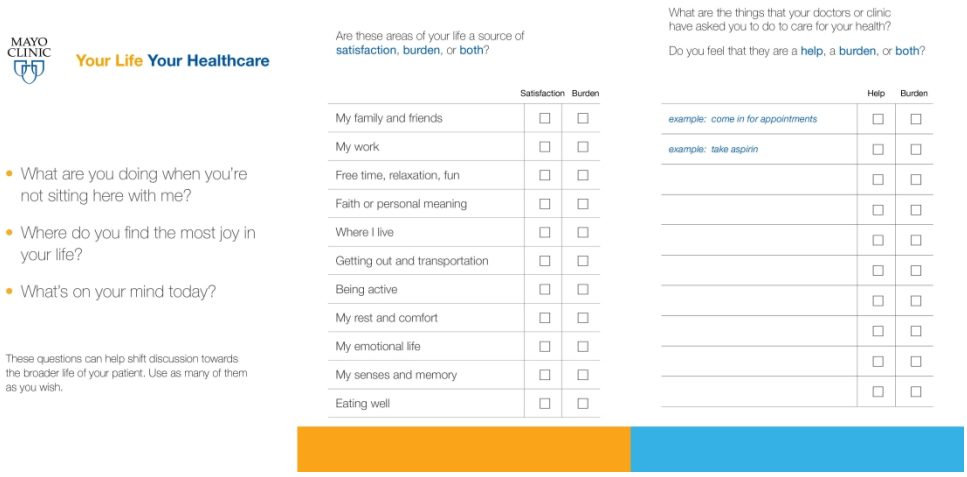

Figure 1: ICAN Discussion Aid

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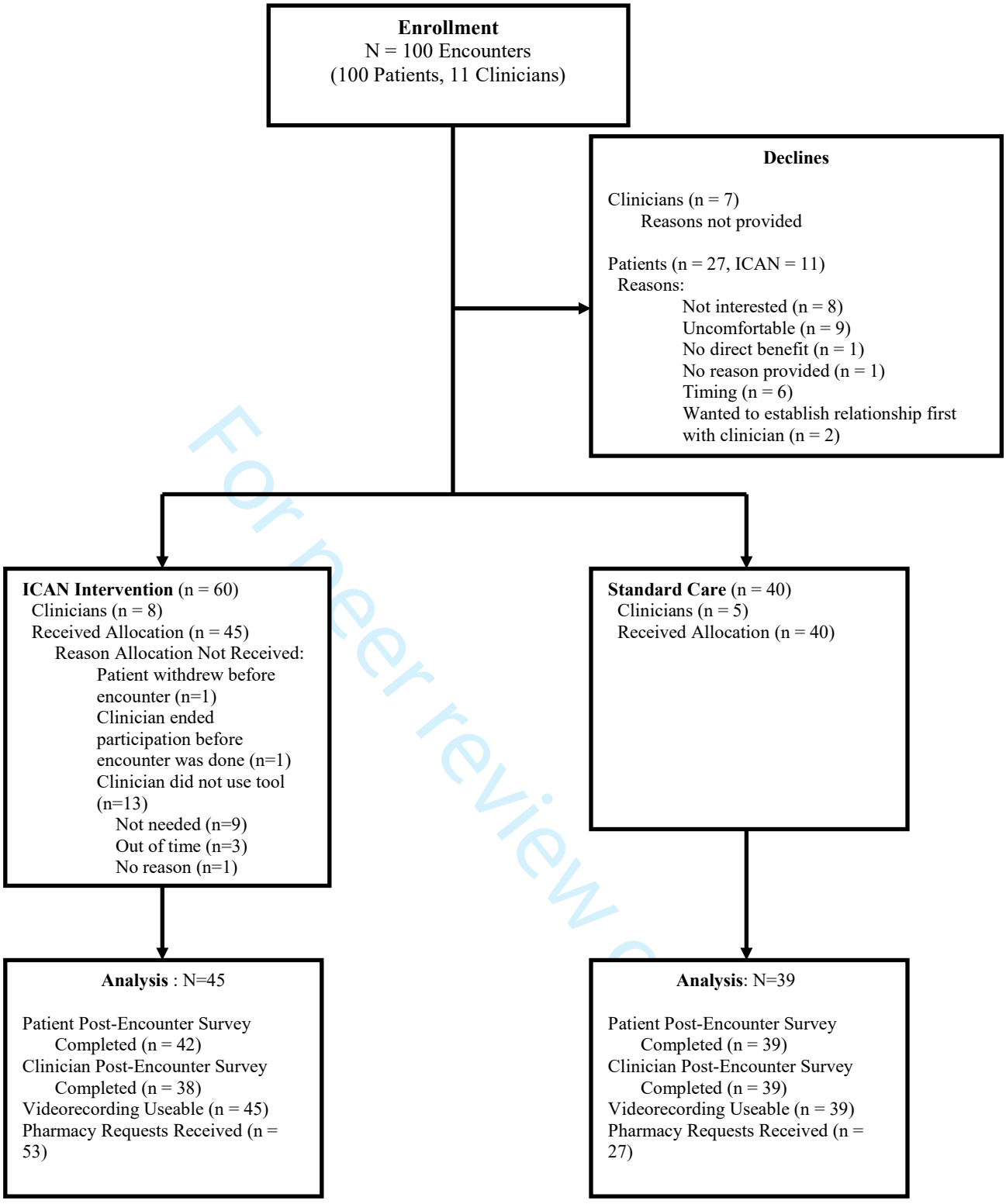

Appendix 1: Pharmaceutical prescription methods and results

Measure

Patients' prescriptions that had been filled were obtained from their pharmacies directly. We collected information on patients' filled prescriptions six months prior to enrollment to six months post-enrollment. Adherence to treatment was assessed for the six months post-enrollment by calculating the percentage of days out of the 180 day period for which a patient had a filled prescription.[23] Medications to treat chronic conditions were considered for inclusion in analysis.

Appendix Table 1: Included Medications

Medication Class	Medication Name
ACE inhibitor	Enalapril Maleate
	Lisinopril
	Ramipril
Alpha blocker	Tamsulosin
	Tamsulosin HCL
Alpha1 adrenergic blocker	Doxazosin Mesylate
Alpha2 delta ligand	Lyrica
Aminoketone antidepressant	Bupropion
	Bupropion HCL
	Bupropion HCL ER
	Bupropion XL
	SR Bupropion
Angiotensin receptor blocker (ARB)	Candesartan
	Lorsartan Potassium
	Losartan
	Losartan -HCTZ
	Losartan HCTZ
	Losartan Potassium
	Losartan-HCTZ
	Valsartan
Antiandrogen	Bicalutamide
Antiarrhythmic drug	Amiodarone
	Flecainide Acetate

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
Anticoagulant	**Enoxaparin Sodium**
	Jantoven
	Warfarin Sodium
	Xarelto
Anticonvulsant	**Carbamazepine**
	Carbamazepine ER
	Gabapentin
	Lamotrigine
	Topiramate
	Zonisamide
Anxiolytic antianxiety agent	**Buspirone**
Atypical antipsychotic	**Latuda**
	Quetiapine
	Quetiapine Fumarate
Beta blocker	**Atendlol Chlorthalidone**
	Atenolol
	Bisoprolol
	Carvedilol
	ER Metoprolol
	Metoprolol ER
	Metoprolol ER Succinate
	Metoprolol SUCC ER
	Metoprolol Tart
	Metoprolol Tartrate
	Metoprololhydrochloroth
	Timolol Maleate
Biguanide	**Metforman**
	Metformin
	Metformin ER
	Metformin HCL

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
	Metformin HCL ER
	metformin
Bisphosphonate	**Alendronate**
	Alendronate Sodium
Calcium channel blocker	**Amlodipine**
	Amlodipine Besylate
	Diltiazem HCL ER
	Nifedipine
	Verapamil HCR ER
Central alpha agonist	**Clonidine HCL**
Central muscle relaxant	**Methocarbamol**
Class 1b antiarrhythmic drug	**Lidocaine**
DDP4 inhibitor + biguanide	**Janumet XR**
Dibenzazepine	**Tegretol XR**
Digitalis glycoside	**Digoxin**
Disease modifying antirheumatic drug (DMARD)	**Hydroxychloroquine Sulfate**
Diuretic	**Hydrochilorothiazide**
	Hydrochlorothiazide
	Metolazone
Fibric acid	**Fenofibrate**
	Fenofibrate Micronized
Janus kinase (JAK) inhibitors	**Xeljanz**
Leukotriene receptor antagonists	**Montelukast Sodium**
Loop diuretic	**Furobemide**
	Furosemide
	Torsemide
Nitrate	**Isosorb Mono ER**
	Isosorbide MN ER
Nonergoline dopamine agonist	**Pramipexole**
Oral diuretic	**Triamterene-HCTZ**

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
P2Y12 inhibitor	**Clopidogrel**
	Clopidogrel Bisulfate
Phenylpiperazine antidepressant	**Nefazodone HCL**
Phosphodiesterase 4 (PDE4) inhibitors	**Otezla**
Potassium sparing diuretic	**Spironolactone**
SNRI	**Desvenlafaxine ER**
	Duloxetine DR
	Duloxetine HCL
	Duloxetine Hcl
	ER Venlafaxine
	Escitalopram Oxalate
	Venafaxine XR
	Venlafaxin XR
	Venlafaxine ER
	Venlafaxine HCL ER
	Venlafaxine XR
SSRI	**Citalopram**
	Citalpram
	Fluoxetine
	Fluoxetine HCL
	Paroxetine
	Paroxetine HCL
	Sertraline
	Sertraline HCL
Selective estrogen receptor modulator (SERM)	**Raloxifene HCL**
	Tamoxifen
Statin	**Atorvastatin**
	Atorvastatin Calcium
	Locastatin
	Lovastatin

Appendix Table 1: Included Medications	
Medication Class	**Medication Name**
	Pravastatin Sodium
	Rosuvastatin Calcium
	Simvastatin
	Vytorin
Sulfonylurea	**Climepiride**
	Glimepiride
	Glipizide
	Glipizide ER
	Glipizide XL
Tetracyclic antidepressant	**Mirtazapine**
Thiazide diuretic	**Chlorthalidone**
Thyroxine; T4 (synthetic)	**Levothroxine**
	Levothyroxine
	Levothyroxine SOD
	Synthroid
Triazolopyridine antidepressant	**Trazodone HCL**
Tricyclic antidepressant	**Amitriptyline HCL**
	Cyclobenzaprine HCL
	Cyclovbenzaprine HCL
	Cyclovenzaprine HCL
	Nortiptyline
	Nortriptyline
	Nortriptyline HCL
Triiodothyronine	**Liothyronine Sodium**
Valeric acid	**Gemfibrozil**
Missing	**Missing**
Other / Unknown	**Amsulosin**
	Isometh-apap-dichlor-
	Metromin HCL
	Oxycodone 5MG IR Tabs

Statistical Analysis

Adherence to medications was assessed by medication class (i.e. if patient had multiple medications within a class, average adherence was calculated). Adherence was modeled using a hierarchical generalized linear model where the outcome was a patients' medication class adherence six months post enrollment. The model was clustered by patient, as patients could have multiple classes of medication, and adjusted by their adherence to the medication class in the six months prior to enrollment and intervention arm. Patients who did not have the medication class in the prior period were set to zero for baseline and a missing indicator was assessed in the model to address this. Patients with missing pharmacy data (e.g. their pharmacy

Adherence Results

Similar rates of medication counts, medication classes and adherence were seen between groups in the six months prior to the encounter of interest (76% of days covered in patients in the ICAN group vs. 71% control)was unreachable for data request) were not included in the analysis.

Appendix Table 2: Analysis of percent of days covered of medication classes by intervention.

	ICAN (N=53)	Pre-Intervention (N=27)	p value
Count of medications prior to encounter			0.57
Mean (SD)	3.6 (2.6)	4.2 (3.3)	
Median (IQR)	3 (2, 5)	4 (2, 5)	
Count of medication classes prior to encounter			0.54
Mean (SD)	3.4 (2.3)	3.9 (2.9)	
Median	3 (1, 5)	4 (2, 5)	
Adherence (PDC) prior to encounter			0.94
Mean (95% CI)	55% (50, 60)	54% (50, 60)	
Count of medications post encounter			0.37
Mean (SD)	3.8 (2.5)	4.1 (2.0)	
Median	3 (2, 5)	4 (3, 5)	
Count of medication classes post encounter			0.36
Mean (SD)	3.6 (2.3)	3.9 (1.8)	
Median	3 (2, 5)	4 (3, 5)	

Appendix Table 2: Analysis of percent of days covered of medication classes by intervention.			
	ICAN (N=53)	Pre-Intervention (N=27)	p value
Adherence (PDC) post encounter			0.56
Mean (95% CI)	75% (70, 80)	71% (60, 80)	
Adjusted adherence (PDC) post encounter^			0.43
Mean (95% CI)	76% (70, 80)	72% (60, 80)	

Acronym: PDC Percent of Days Covered

* Prior and post encounter periods are each 6 months long.

^ ANCOVA with random effect of clinician and adjusted by prior 6 months adherence and intervention.