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

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

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Manuscripts

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3 **Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and**
4 **Feasibility Study of the ICAN Discussion Aid**
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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 patients⁶⁻⁸. 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

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

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12 To pilot test the ICAN Discussion Aid, we conducted a pre-test versus post-test
13 intervention study.
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16 *2.1. Ethics*

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18 All study procedures were approved by the Mayo Clinic IRB (14-008621); patient and
19 clinician participants consented for data collection procedures.
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22 *2.2. Participant Eligibility and Recruitment*

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24 Clinicians were recruited from two clinical sites in the Midwest and were eligible for
25 participation if they regularly saw patients with chronic conditions. Clinicians were consented
26 for participation either at a lunch-hour clinical practice meeting or immediately before their first
27 eligible patient. Adult patients were eligible if they had one or more chronic conditions, no major
28 barriers to consent (e.g. cognitive impairment), and were seeing a clinician who had agreed to
29 participate. Patients were approached immediately before the encounter with their clinician.
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32 *2.3 Study Procedures*

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34 After both clinician and patient were enrolled in the study, a trained study coordinator set
35 up a small video camera (i.e., FlipCam, GoPro) to record the clinic visit. Patients and clinicians
36 could turn the video camera off at any time if they felt uncomfortable, and the video camera was
37 always turned around or off during physical exams. Following the encounter, both patient and
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3 clinician were given a survey to complete immediately or return in a postage-paid return
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5 envelope. The study coordinator followed-up on surveys not returned within one week. The first
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7 40 clinical encounters were usual care. After the first 40 encounters, clinicians were then trained
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9 during a standing meeting or individually on how to use the ICAN Discussion Aid. The
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11 remaining 60 clinical encounters were intended to be ICAN encounters.
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15 16 *2.4. Intervention: The ICAN Discussion Aid*

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18 The study coordinator provided instructions for the patient to complete the ICAN
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20 Discussion Aid (**Figure 1**) before the clinician entered the room. When the clinician entered the
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22 room, he or she would select one of three opening questions to elicit responses from the patient,
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24 and would then explore the information that the patient provided in ICAN by asking “What
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26 stands out to you on this sheet you filled?” Clinicians were instructed to discuss that issue alone
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28 and connect it to the reason for the visit that day. Clinical conversation was expected to proceed
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30 as usual with incorporation of the ICAN information.
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34 35 *2.5. Measures*

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37 Clinician degree, position, and gender were collected at baseline. Patient characteristics
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39 of age, sex and marital status were abstracted from the medical record. To assess *perceived*
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41 *success* of the encounter, we used the Consultation Care Measure (CCM), a valid and
42
43 discriminating tool to measure communication and partnership within a single encounter,
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45 previously correlated with patient satisfaction, enablement, and reduced symptom burden.¹⁹ The
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47 measure asks patients to what extent they agree with statements about the doctor such as he/she
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49 “was interested in what I thought the problem was.”¹⁹ For clinician surveys, we used a modified
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51 version of the patient CCM, adjusted to the clinician perspective, which was not previously
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3 validated. For example, the patient might be asked the extent to which they felt the clinician
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5 “was careful to explain the plan of treatment.” Whereas the clinician would be asked the extent
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7 to which they agreed with the statement that they felt that they “were careful to explain the plan
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9 of treatment.” To assess *feasibility* of ICAN use, we asked clinicians to report how easy or
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11 difficult the aid was to use in their encounter on a 5-point scale, from very easy to very difficult.
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13 If clinicians marked difficult or very difficult, they were prompted to write a brief description of
14
15 why. To assess *adherence*, patients pharmaceutical records were collected as a means to provide
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17 estimates of baseline adherence amongst patients in this population, and of whether using ICAN
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19 potentially effects adherence through the tailoring of patient care plans to their life context.
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21 Given the hypothesis generating nature of the adherence data, the methods and results are
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23 provided in **Appendix 1**.

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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

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3 opening questions typically used in ICAN, designed to elicit the existence of competing priorities
4 that could potentially limit the capacity for self-care or treatment, sources of joy in patients'
5 lives, and immediate concerns (medical and non-medical). To assess *impact on length of visit*,
6 we compared lengths of video recording.
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13 *2.7. Analyses*

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16 All statistical analyses were conducted in SAS (SAS Institute Inc., Version 9.4, Cary, NC,
17 USA) and Stata (StataCorp, Release 15, College Station, TX). Videographic coding was done
18 using Noldus Observer XT (version 11, Leesburg, VA). Patient and clinical encounter
19 characteristics were compared between ICAN and control encounters using a t-test for
20 continuous variables and a chi-square test for categorical variables. To explore differences in
21 patient and clinician perceived success of an encounter, we subtracted unadjusted clinician
22 scores from unadjusted patient scores, and tested for changes in the perceived success gap
23 between ICAN and control encounters using a Wilcoxon Rank-Sum test. To test for differences
24 across issues discussed in videos where patients and clinicians used ICAN versus those recorded
25 in control encounters, we used a negative binomial model accounting for clustering within
26 clinicians.
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43 *2.8 Patient and Public Involvement*

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

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3 Eleven clinicians were enrolled from two primary care clinics within the Midwest, United
4 States starting in October 2015. Seven clinicians approached declined enrollment, without
5 providing a reason. The clinicians were primarily female (N=7, 64%) and were primarily
6 physicians, with one nurse practitioner and two physician assistants. Patient enrollment began
7 October 2015 and ended February 2017. 100 patients consented to participate (ICAN n=60).
8 Detailed enrollment information is depicted in **Figure 2**. Of the eleven clinicians participating,
9 one had all control encounters and five had all ICAN encounters. Patient characteristics are
10 depicted in **Table 1**. Encounter length did not significantly differ between ICAN and control
11 encounters.
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25 *3.1. Clinician reported feasibility of ICAN*

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27 Clinicians found the tool feasible to use in the majority of encounters. 62% reported it
28 very easy or easy, 32% reported it as neither easy nor difficult, and 5% reported it was difficult
29 to use in that encounter. There were two encounters where it was reported as difficult by
30 different clinicians. For one encounter the clinician stated, "Unfortunately, this made her
31 appointment go over by about 30 minutes. It was good we discussed issues with the portal [*an*
32 *online platform that allows patients to access their health information*] and her life and stressors
33 but it wasn't a big concern (why it wasn't a reason for the appointment) but we spent a good deal
34 of time on it." Upon further review of this video, it appears that the primary reason that the
35 encounter lasted substantially longer than planned was a lack of fidelity to ICAN training. After
36 the clinician asked the patient what stood out to her from ICAN, she continued to elicit
37 information about each burden listed by the patient, rather than connect the patient's response to
38 the remainder of the clinical visit. Addressing the two key issues the patient brought up, work
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3 stress and being active, took approximately five and a half minutes in total. Following that, the
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5 clinician spent an additional five and a half minutes reviewing the other items on the tool.
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8 In the second encounter, the clinician stated, “I enjoy the learning and conversation
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10 obtained from form [sic] but didn't have the extra time in schedule [sic] necessary to address
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12 each issue - easily added another 15-20 minutes to appointment.” In this encounter, the patient
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14 indicated that her emotional life was both a source of satisfaction and a burden. The clinician
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16 enquired further and thus provided the patient with an opportunity to talk about her prolonged
17
18 grief after the loss of her spouse and her concerns about possible depression. In response the
19
20 clinician screened the patient for potential depression. Total time using the tool and discussing
21
22 that issue took four minutes of the total visit. The patient was scheduled for a 45 minute general
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24 medical exam, and the total video recorded visit time was 26 minutes, which did not include the
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26 physical exam at the end of the encounter.
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31 32 *3.2. Survey Results* 33 34

35 We did not find any items with significant differences between patients in either cohort
36
37 for the consultation care measure (**Table 2**). When comparing patients and clinicians across the
38
39 consultation care measure, among the items that overlapped, clinicians tended to score
40
41 themselves poorer than patients. This was more prevalent when the ICAN tool was used (**Table**
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43 **3**).
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47 48 *3.3. Videographic Results* 49

50 Issues discussed during clinical encounters did significantly differ between ICAN and
51
52 control encounters in multiple domains (**Table 4**). Specifically, discussions about being active,
53
54 diet, and taking medications were discussed significantly more frequently in ICAN encounters.
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3 Discussions about administrative treatment work, other treatment work, family, living
4 arrangements, and comfort were discussed significantly less frequently in ICAN encounters. We
5 noticed that often topics about family were used as conversation fillers in control encounters,
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7 whereas there may have been less room for this when patients were prompted to bring up issues
8 that mattered most to them.
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16 **4. Discussion and Conclusion**

17 *4.1. Summary of Findings*

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20 Within this pilot trial, clinicians found the ICAN Discussion Aid to be a tool they could
21 feasibly adopt into everyday practice and which did not impact the length of the visit. Patients
22 discussed diet, being active, and taking medications more often in ICAN encounters.
23 Additionally, clinicians elicited competing priorities using ICAN opening questions that were
24 never elicited during the opening of control encounters. While clinicians rated the perceived
25 success of their encounters poorer than their patients (CCM score), and the gap between patient
26 and clinician perceived success was larger ICAN encounters, the difference was not significant.
27 No difference was seen for adherence to prescription medications.
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42 *4.2. Limitations and Strengths*

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45 These findings cannot be interpreted without considering the limitations in this study
46 design. First, this study was a small before-after pilot study which limits our ability to draw
47 statistical inferences that would be possible in a larger trial with a randomized design. The study
48 was not powered to assess clinical significance for patient-reported outcomes nor prescription
49 adherence and a lack of difference found is not indicative of one not existing. Furthermore, the
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3 study occurred within a single healthcare system in the Midwest with a fairly homogenous
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5 patient population of mostly high or middle socioeconomic status, which limits the
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7 generalizability of the specific changes in topics present in ICAN conversations versus usual care
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9 conversations. However, the small size of the study allowed us to pursue video-recording of all
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11 encounters, which allowed for deeper exploration of ICAN's impact on conversations and to
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13 point to additional needs for future implementation and testing of ICAN in practice that would
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15 have been more difficult in a larger multi-site study.
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20 *4.3. Practice Implications*

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23 Feasibility of ICAN use is an important finding on its own, given previously reported
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25 challenges by clinicians in providing patient-centered care and participating in shared decision
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27 making for populations living with MCC.²² Furthermore, the difference in the topics brought up
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29 in ICAN encounters suggests that patients are indeed more likely to be able to voice their topics
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31 of choice, in an area where poor communication has been a noted frustration amongst patients.²³
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33 Diet, being active, and taking medications are not surprising topics to be most important to
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35 patients in this setting and population (suburban, Midwest, academic medical center). However,
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37 these topics have been noted as important treatment burden factors for patients in other diverse
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39 samples; patients noted that they were aware their clinicians wanted them to eat healthier or
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41 exercise more frequently, but important barriers existed of which their clinicians were unaware.²⁴
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43 Furthermore, in a previous study of patient-clinician concordance, patients were more likely than
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45 clinicians to rank being active as one of their top three health concerns.²⁵ Future research should
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47 examine whether the topics discussed more often are different in other clinical settings (e.g. rural
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49 and urban), with different populations (e.g. unsalaried clinicians, underserved patients), and what
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51 clinicians can do in clinical encounters with this information.
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3 Examining the two encounters noted as difficult for clinicians yielded important
4 information about ICAN implementation challenges. The encounter where additional time was
5 used to discuss all ICAN items suggests that additional training may be needed for clinicians to
6 illustrate how to connect the initial question of “What stands out to you?” to the clinical reason
7 for the appointment, and how to continue the use of the discussion aid at future encounters. In
8 the encounter in which the patient was able to discuss potential concerns of depression, the
9 clinician noted that this added an additional 15 – 20 minutes to the encounter, whereas the actual
10 discussion took less than five minutes. The perceived duration may have felt longer than the
11 actual duration because of the heavy nature of the topic discussed. Past research in primary care
12 patients with multi-morbidity has shown that clinician comfort level with these types of difficult
13 topics is low and that in practicing a traditional “additive-sequential model,” where each problem
14 is treated independently and prioritized, these issues may never get acknowledged.^{15,26} Therefore,
15 the implementation of ICAN can provide an opportunity to train clinicians to address potentially
16 difficult topics, manage their expectations of those discussions, and learn how to successfully
17 have those conversations.
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38 *4.4. Conclusion*

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

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Included Figures

Figure 1: ICAN Discussion Aid

Figure 2: Detailed Enrollment Information

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	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)	

27 [^]All enrolled patients.

28 *3 patients in intervention missing data on characteristics.

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36 **Table 2: CCM Patient Scores**

	ICAN (N=42)	Pre-Intervention (N=39)	Total (N=81)
Overall score			
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)	

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47 *Adjusted by clinician clustering; lower scores = better

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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.

	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

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- What are you doing when you're not sitting here with me?
- Where do you find the most joy in your life?
- What's on your mind today?

These questions can help shift discussion towards the broader life of your patient. Use as many of them as you wish.

Are these areas of your life a source of satisfaction, burden, or both?

	Satisfaction	Burden
My family and friends	<input type="checkbox"/>	<input type="checkbox"/>
My work	<input type="checkbox"/>	<input type="checkbox"/>
Free time, relaxation, fun	<input type="checkbox"/>	<input type="checkbox"/>
Faith or personal meaning	<input type="checkbox"/>	<input type="checkbox"/>
Where I live	<input type="checkbox"/>	<input type="checkbox"/>
Getting out and transportation	<input type="checkbox"/>	<input type="checkbox"/>
Being active	<input type="checkbox"/>	<input type="checkbox"/>
My rest and comfort	<input type="checkbox"/>	<input type="checkbox"/>
My emotional life	<input type="checkbox"/>	<input type="checkbox"/>
My senses and memory	<input type="checkbox"/>	<input type="checkbox"/>
Eating well	<input type="checkbox"/>	<input type="checkbox"/>

What are the things that your doctors or clinic have asked you to do to care for your health?

Do you feel that they are a help, a burden, or both?

	Help	Burden
<i>example: come in for appointments</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>example: take aspirin</i>	<input type="checkbox"/>	<input type="checkbox"/>
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Figure 1: ICAN Discussion Aid
419x215mm (300 x 300 DPI)

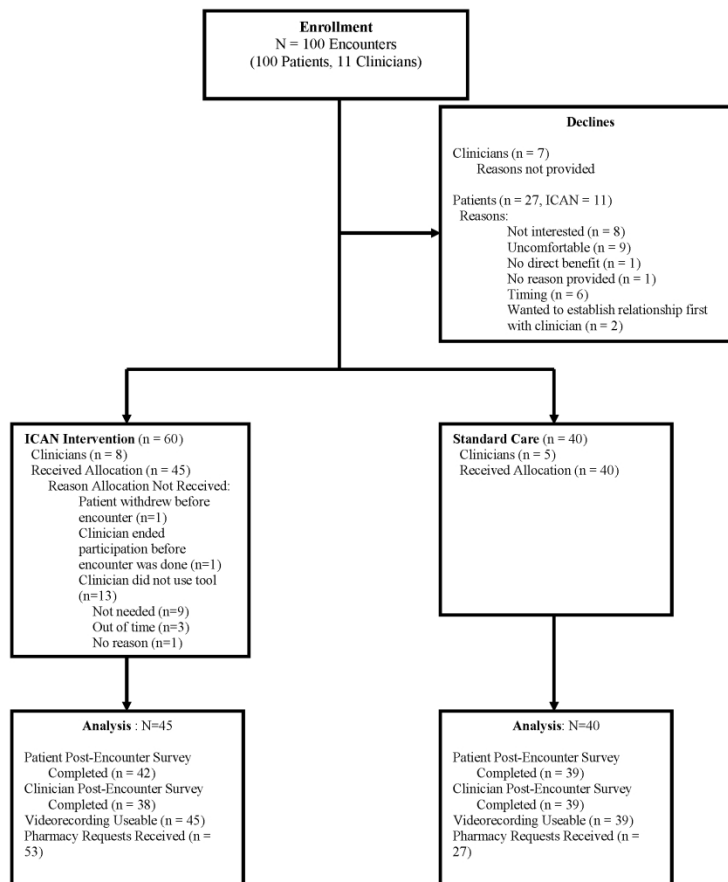


Figure 2: Detailed Enrollment Information

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	
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	Hydrochlorothiazide
	Hydrochlorothiazide
	Metolazone
Fibric acid	Fenofibrate
	Fenofibrate Micronized
Janus kinase (JAK) inhibitors	Xeljanz
Leukotriene receptor antagonists	Montelukast Sodium
Loop diuretic	Furobemide
	Furosemide
	Torseamide
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	Spirolactone
SNRI	Desvenlafaxine ER
	Duloxetine DR
	Duloxetine HCL
	Duloxetine Hcl
	ER Venlafaxine
	Escitalopram Oxalate
	Venlafaxine XR
	Venlafaxin XR
	Venlafaxine ER
	Venlafaxine HCL ER
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
	Cyclovenzaprine HCL
	Cyclovenzaprine HCL
	Nortriptyline
	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

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Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Communication
Keywords:	patient-centered care, minimally disruptive medicine, healthcare communication, chronic disease, multimorbidity

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Manuscripts

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3 **Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and**
4 **Feasibility Study of the ICAN Discussion Aid**
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49 **Word Count:** 2,680; 2 Figures, 4 Tables, 1 Appendix
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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 patients⁶⁻⁸. 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,

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3 previously used to develop decision aids¹⁸ and was grounded in the Cumulative Complexity
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5 Model, which states that patients living with chronic illness must enact both patient and life work
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7 with limited capacity.¹⁹ When workload exceeds patient capacity, it affects patients' abilities to
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9 access and use healthcare and enact self-care, in turn effecting their health outcomes.¹⁹ In
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11 addition to worsening health outcomes, unaddressed workload-capacity imbalance can lead to a
12
13 vicious cycle of added treatment burden and illness burden.¹⁹
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18 To date, the ICAN Discussion Aid remains untested in terms of its impact on the
19
20 discussion of patient workload, capacity, and treatment burden in the clinical encounter. We
21
22 hypothesize that if ICAN proves feasible in busy primary care and positively impacts the clinical
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24 encounter with greater discussion of patients' context, it could spark treatment plans that better
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26 fit patients' lives, with downstream impact on patient health outcomes and quality of life.
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29 30 *1.2. Aim*

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33 We aimed to evaluate the feasibility of using the ICAN Discussion Aid in primary care
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35 and to estimate its impact on clinical care, including patient and clinician-perceived success of
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37 visits, length of visits, and topics of conversation.
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40 41 **2. Methods**

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44 To pilot test the ICAN Discussion Aid, we conducted a pre-test versus post-test
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46 intervention study.
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49 50 *2.1. Ethics*

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

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3 stands out to you on this sheet you filled?” Clinicians were instructed to discuss that issue alone
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5 and connect it to the reason for the visit that day. Clinical conversation was expected to proceed
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7 as usual with incorporation of the ICAN information.
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10 2.5. Measures

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13 Clinician degree, position, and gender were collected at baseline. Patient characteristics
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15 of age, sex and marital status were abstracted from the medical record. To assess *perceived*
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17 *success* of the encounter, we used the Consultation Care Measure (CCM), a valid and
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19 discriminating tool to measure communication and partnership within a single encounter,
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21 previously correlated with patient satisfaction, enablement, and reduced symptom burden.²⁰ The
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23 measure asks patients to what extent they agree with statements about the doctor such as he/she
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25 “was interested in what I thought the problem was.”²⁰ For clinician surveys, we used a modified
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27 version of the patient CCM, adjusted to the clinician perspective, which was not previously
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29 validated. For example, the patient might be asked the extent to which they felt the clinician
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31 “was careful to explain the plan of treatment.” Whereas the clinician would be asked the extent
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33 to which they agreed with the statement that they felt that they “were careful to explain the plan
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35 of treatment.” To assess *feasibility* of ICAN use, we asked clinicians to report how easy or
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37 difficult the aid was to use in their encounter on a 5-point scale, from very easy to very difficult.
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39 If clinicians marked difficult or very difficult, they were prompted to write a brief description of
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41 why. To assess *adherence*, patients pharmaceutical records were collected as a means to provide
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43 estimates of baseline adherence amongst patients in this population, and of whether using ICAN
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45 potentially effects adherence through the tailoring of patient care plans to their life context.
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47 Given the hypothesis generating nature of the adherence data, the methods and results are
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49 provided in **Appendix 1**.
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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., Version 9.4, 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

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3 patient and clinician perceived success of an encounter, we subtracted unadjusted clinician
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5 scores from unadjusted patient scores, and tested for changes in the perceived success gap
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7 between ICAN and control encounters using a Wilcoxon Rank-Sum test. To test for differences
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9 across issues discussed in videos where patients and clinicians used ICAN versus those recorded
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11 in control encounters, we used a negative binomial model accounting for clustering within
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13 clinicians.
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16 17 18 *2.8 Patient and Public Involvement*

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21 The Knowledge and Evaluation Research Unit Patient Advisory Group participated in the
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23 design of the ICAN Discussion Aid, ensuring its relevance to patients living with chronic
24
25 conditions and its ease of use. They were not consulted for the research design of the pilot study.
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28 **3. Results**

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31 Eleven clinicians were enrolled from two primary care clinics within the Midwest, United
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33 States starting in October 2015. Seven clinicians approached declined enrollment, without
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35 providing a reason. The clinicians were primarily female (N=7, 64%) and were primarily
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37 physicians, with one nurse practitioner and two physician assistants. Patient enrollment began
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39 October 2015 and ended February 2017. 100 patients consented to participate (ICAN n=60).
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41 Detailed enrollment information is depicted in **Figure 2**. Of the eleven clinicians participating,
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43 one had all control encounters and five had all ICAN encounters. Patient characteristics are
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45 depicted in **Table 1**. Encounter length did not significantly differ between ICAN and control
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47 encounters.
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51 52 53 *3.1. Clinician reported feasibility of ICAN*

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

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19 In the second encounter, the clinician stated, "I enjoy the learning and conversation
20 obtained from form [*sic*] but didn't have the extra time in schedule [*sic*] necessary to address
21 each issue - easily added another 15-20 minutes to appointment." In this encounter, the patient
22 indicated that her emotional life was both a source of satisfaction and a burden. The clinician
23 enquired further and thus provided the patient with an opportunity to talk about her prolonged
24 grief after the loss of her spouse and her concerns about possible depression. In response the
25 clinician screened the patient for potential depression. Total time using the tool and discussing
26 that issue took four minutes of the total visit. The patient was scheduled for a 45 minute general
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3 Within this pilot trial, clinicians found the ICAN Discussion Aid to be a tool they could
4 feasibly adopt into everyday practice and which did not impact the length of the visit. Patients
5 discussed diet, being active, and taking medications more often in ICAN encounters.
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10 Additionally, clinicians elicited competing priorities using ICAN opening questions that were
11 never elicited during the opening of control encounters. While clinicians rated the perceived
12 success of their encounters poorer than their patients (CCM score), and the gap between patient
13 and clinician perceived success was larger ICAN encounters, the difference was not significant.
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19 No difference was seen for adherence to prescription medications.
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22 *4.2. Limitations and Strengths*

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26 These findings cannot be interpreted without considering the limitations in this study
27 design. First, this study was a small before-after pilot study which limits our ability to draw
28 statistical inferences that would be possible in a larger trial with a randomized design. The study
29 was not powered to assess clinical significance for patient-reported outcomes nor prescription
30 adherence and a lack of difference found is not indicative of one not existing. Furthermore, the
31 study occurred within a single healthcare system in the Midwest with a fairly homogenous
32 patient population of mostly high or middle socioeconomic status, which limits the
33 generalizability of the specific changes in topics present in ICAN conversations versus usual care
34 conversations. However, the small size of the study allowed us to pursue video-recording of all
35 encounters, which allowed for deeper exploration of ICAN's impact on conversations and to
36 point to additional needs for future implementation and testing of ICAN in practice that would
37 have been more difficult in a larger multi-site study.
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53 *4.3. Practice Implications*

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3 Feasibility of ICAN use is an important finding on its own, given previously reported
4 challenges by clinicians in providing patient-centered care and participating in shared decision
5 making for populations living with MCC.²³ Furthermore, the difference in the topics brought up
6 in ICAN encounters suggests that patients are indeed more likely to be able to voice their topics
7 of choice, in an area where poor communication has been a noted frustration amongst patients.²⁴
8 Diet, being active, and taking medications are not surprising topics to be most important to
9 patients in this setting and population (suburban, Midwest, academic medical center). However,
10 these topics have been noted as important treatment burden factors for patients in other diverse
11 samples; patients noted that they were aware their clinicians wanted them to eat healthier or
12 exercise more frequently, but important barriers existed of which their clinicians were unaware.²⁵
13 Furthermore, in a previous study of patient-clinician concordance, patients were more likely than
14 clinicians to rank being active as one of their top three health concerns.²⁶ Future research should
15 examine whether the topics discussed more often are different in other clinical settings (e.g. rural
16 and urban), with different populations (e.g. unsalaried clinicians, underserved patients), and what
17 clinicians can do in clinical encounters with this information.
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38 Ultimately, the discussion of topics of greater importance to patients and their competing
39 priorities is important as it could lead to better tailoring of treatment plans to patients' context,
40 improving patients' workload-capacity balance in managing chronic illness. As mentioned
41 earlier, the Cumulative Complexity Model postulates that workload-capacity balance impacts
42 patients' abilities to access and use healthcare and enact self-care, with downstream impact on
43 their health outcomes.¹⁹ Furthermore, communication models, such as the one proposed by Street
44 et al. have postulated the pathways from patient-clinician communication to patient outcomes.²⁷
45 For example, Street's model illustrates that communication functions supported by ICAN such as
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3 managing uncertainty, fostering relationships, and enabling self-management can impact
4 proximal outcomes such as patient trust and “feeling known,” with downstream consequences on
5 self-care skills, adherence, and ultimately health outcomes.²⁷ ICAN is a general discussion aid
6 for use in chronic illness, intended to provide insight into the personal, social, material, and
7 spiritual aspects of the patient’s situation; it can be used in conjunction with the many available
8 decision-specific conversation aids.²⁸ For example, an ICAN conversation may illuminate that a
9 patient finds their overall medication regimen particularly burdensome, and this may spark a
10 treatment-specific conversation about choosing a different treatment in replacement of a current
11 one or inform the decision to add or not add another medication to the list. A good example of
12 the use of ICAN and a treatment decision aid is available on the web.²⁹ Used in this way,
13 clinicians may fully understand patients’ competing priorities as well as treatment-specific
14 values and preferences, and therefore, be able to co-create with them treatment plans that fit their
15 context and allow them to lead quality lives to the fullest extent.
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34 Examining the two encounters noted as difficult for clinicians yielded important
35 information about ICAN implementation challenges. The encounter where additional time was
36 used to discuss all ICAN items suggests that additional training may be needed for clinicians to
37 illustrate how to connect the initial question of “What stands out to you?” to the clinical reason
38 for the appointment, and how to continue the use of the discussion aid at future encounters. In
39 the encounter in which the patient was able to discuss potential concerns of depression, the
40 clinician noted that this added an additional 15 – 20 minutes to the encounter, whereas the actual
41 discussion took less than five minutes. The perceived duration may have felt longer than the
42 actual duration because of the heavy nature of the topic discussed. Past research in primary care
43 patients with multi-morbidity has shown that clinician comfort level with these types of difficult
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3 topics is low and that in practicing a traditional “additive-sequential model,” where each problem
4 is treated independently and prioritized, these issues may never get acknowledged.^{15,30} Therefore,
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6 the implementation of ICAN can provide an opportunity to train clinicians to address potentially
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8 difficult topics, manage their expectations of those discussions, and learn how to successfully
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10 have those conversations. Specifically, this requires attention and clinician exposure in future
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12 ICAN trainings to the potentially uncomfortable and off-script conversations that may occur as a
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14 result of using the aid, as well as practice in having those conversations first in safe spaces, such
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16 as with peers and trainers, prior to real-life clinical encounters.
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22 *4.4. Conclusion*

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

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47 KRB was responsible for study design, overall study execution, analysis, and the draft
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49 manuscript. CCD and AT conducted videographic analysis and provided critical revisions for the
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51 manuscript. MB and RG conducted statistical analysis, created tables, and drafted the statistical
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53 sections of the manuscript. EB was responsible for study coordination of the study and data
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3 collection procedures. PO assisted with data cleaning procedures, drafting of the manuscript, and
4
5 critical revisions to the manuscript. SVA served as clinical champion for the study and provided
6
7 critical revisions to the manuscript. KS provided revisions to the manuscript and data
8
9 visualization. VMM assisted KRB with study design and oversight of the project.
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13 *Conflicts of Interests*

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16 The authors of this manuscript have no conflicts of interests to report.
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21
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23
24 Arlene Kogod Center for Aging.
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28 *Data Availability*

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31 All data for this study are published within this manuscript and its supplementary materials. No
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33 additional unpublished data is available.
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36 *Included Figures*

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39 Figure 1: ICAN Discussion Aid
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43 Figure 2: Detailed Enrollment Information
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	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)	

27 [^]All enrolled patients.

28 *3 patients in intervention missing data on characteristics.

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36 **Table 2: CCM Patient Scores**

	ICAN (N=42)	Pre-Intervention (N=39)	Total (N=81)
Overall score			
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)	

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47 *Adjusted by clinician clustering; lower scores = better

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For peer review only

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.

	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

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- What are you doing when you're not sitting here with me?
- Where do you find the most joy in your life?
- What's on your mind today?

These questions can help shift discussion towards the broader life of your patient. Use as many of them as you wish.

Are these areas of your life a source of satisfaction, burden, or both?

	Satisfaction	Burden
My family and friends	<input type="checkbox"/>	<input type="checkbox"/>
My work	<input type="checkbox"/>	<input type="checkbox"/>
Free time, relaxation, fun	<input type="checkbox"/>	<input type="checkbox"/>
Faith or personal meaning	<input type="checkbox"/>	<input type="checkbox"/>
Where I live	<input type="checkbox"/>	<input type="checkbox"/>
Getting out and transportation	<input type="checkbox"/>	<input type="checkbox"/>
Being active	<input type="checkbox"/>	<input type="checkbox"/>
My rest and comfort	<input type="checkbox"/>	<input type="checkbox"/>
My emotional life	<input type="checkbox"/>	<input type="checkbox"/>
My senses and memory	<input type="checkbox"/>	<input type="checkbox"/>
Eating well	<input type="checkbox"/>	<input type="checkbox"/>

What are the things that your doctors or clinic have asked you to do to care for your health?

Do you feel that they are a help, a burden, or both?

	Help	Burden
<i>example: come in for appointments</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>example: take aspirin</i>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>



Figure 1: ICAN Discussion Aid

419x215mm (300 x 300 DPI)

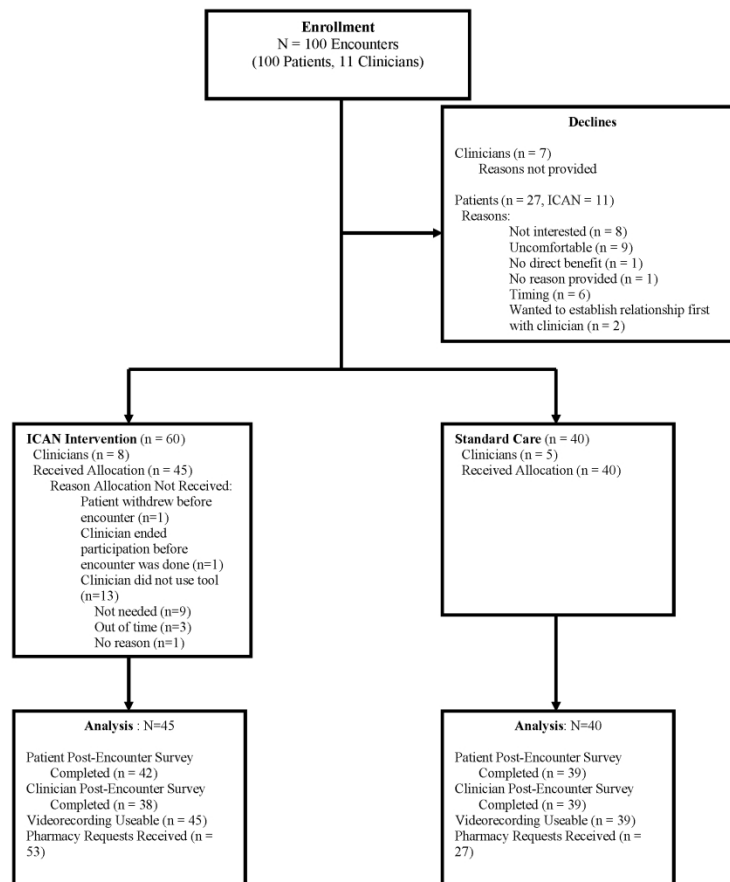


Figure 2: Detailed Enrollment Information

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	
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	Hydrochlorothiazide
	Hydrochlorothiazide
	Metolazone
Fibric acid	Fenofibrate
	Fenofibrate Micronized
Janus kinase (JAK) inhibitors	Xeljanz
Leukotriene receptor antagonists	Montelukast Sodium
Loop diuretic	Furobemide
	Furosemide
	Torseamide
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	Spirolactone
SNRI	Desvenlafaxine ER
	Duloxetine DR
	Duloxetine HCL
	Duloxetine Hcl
	ER Venlafaxine
	Escitalopram Oxalate
	Venlafaxine XR
	Venlafaxin XR
	Venlafaxine ER
	Venlafaxine HCL ER
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
	Cyclovenzaprine HCL
	Cyclovenzaprine HCL
	Nortriptyline
	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

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

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3 **Changing Conversations in Primary Care for Patients Living with Chronic Conditions: A Pilot and**
4 **Feasibility Study of the ICAN Discussion Aid**
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53 **Word Count:** 3,532; 2 Figures, 4 Tables, 1 Appendix
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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 patients⁶⁻⁸. 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,

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2
3 previously used to develop decision aids¹⁸ and was grounded in the Cumulative Complexity
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5 Model, which states that patients living with chronic illness must enact both patient and life work
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7 with limited capacity.¹⁹ When workload exceeds patient capacity, it affects patients' abilities to
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9 access and use healthcare and enact self-care, in turn effecting their health outcomes.¹⁹ In
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11 addition to worsening health outcomes, unaddressed workload-capacity imbalance can lead to a
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13 vicious cycle of added treatment burden and illness burden.¹⁹
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18 To date, the ICAN Discussion Aid remains untested in terms of its impact on the
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20 discussion of patient workload, capacity, and treatment burden in the clinical encounter. We
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22 hypothesize that if ICAN proves feasible in busy primary care and positively impacts the clinical
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24 encounter with greater discussion of patients' context, it could spark treatment plans that better
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26 fit patients' lives, with downstream impact on patient health outcomes and quality of life.
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29 30 *1.2. Aim*

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33 We aimed to evaluate the feasibility of using the ICAN Discussion Aid in primary care
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35 and to estimate its impact on clinical care, including patient and clinician-perceived success of
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37 visits, length of visits, and topics of conversation.
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40 41 **2. Methods**

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44 To pilot test the ICAN Discussion Aid, we conducted a pre-test versus post-test
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46 intervention study.
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49 50 *2.1. Ethics*

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

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3 why. To assess *adherence*, patients pharmaceutical records were collected as a means to provide
4 estimates of baseline adherence amongst patients in this population, and of whether using ICAN
5 potentially effects adherence through the tailoring of patient care plans to their life context.
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10 Given the hypothesis generating nature of the adherence data, the methods and results are
11 provided in **Appendix 1**.
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14 15 2.6. Videographic Coding Scheme

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18 To assess ICAN's *impact on clinical conversation topics*, we created an a priori video
19 coding scheme, in which we coded each instance where the following topics were brought up:
20 family, friends, free time, faith, living situation, being active, rest, comfort, emotional life,
21 senses, memory, eating well, taking medications, making appointments, getting to appointments,
22 administrative treatment work (e.g., dealing with insurance/billing, communicating with
23 pharmacies), prescribed behaviors (e.g. getting mammograms, exercising a certain number of
24 minutes per week), and other treatment work (i.e, work that the patient was asked to do but that
25 did not fit into these other categories). Life issues listed in the coding scheme were those shown
26 on ICAN and previously illustrated as important components of patient capacity from earlier
27 work.^{17,21} Treatment burden issues listed in the coding scheme were derived from typical issues
28 listed in the development of ICAN and a taxonomy of treatment burden.^{17,22} We also coded for
29 opening questions typically used in ICAN, designed to elicit the existence of competing priorities
30 that could potentially limit the capacity for self-care or treatment, sources of joy in patients'
31 lives, and immediate concerns (medical and non-medical). To assess *impact on length of visit*,
32 we compared lengths of video recording.
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54 2.7. Analyses

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3 All statistical analyses were conducted in SAS (SAS Institute Inc., Version 9.4, Cary, NC,
4 USA) and Stata (StataCorp, Release 15, College Station, TX). Videographic coding was done
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6 using Noldus Observer XT (version 11, Leesburg, VA). Patient and clinical encounter
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8 characteristics were compared between ICAN and control encounters using a t-test for
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10 continuous variables and a chi-square test for categorical variables. To explore differences in
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12 patient and clinician perceived success of an encounter, we subtracted unadjusted clinician
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14 scores from unadjusted patient scores, and tested for changes in the perceived success gap
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16 between ICAN and control encounters using a Wilcoxon Rank-Sum test. To test for differences
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18 across issues discussed in videos where patients and clinicians used ICAN versus those recorded
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20 in control encounters, we used a negative binomial model accounting for clustering within
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22 clinicians.
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29 *2.8 Patient and Public Involvement*

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

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42 Eleven clinicians were enrolled from two primary care clinics within the Midwest, United
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44 States starting in October 2015. Seven clinicians approached declined enrollment, without
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46 providing a reason. The clinicians were primarily female (N=7, 64%) and were primarily
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48 physicians, with one nurse practitioner and two physician assistants. Patient enrollment began
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50 October 2015 and ended February 2017. 100 patients consented to participate (ICAN n=60).
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52 Detailed enrollment information is depicted in **Figure 2**. Of the eleven clinicians participating,
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3 one had all control encounters and five had all ICAN encounters. Patient characteristics are
4 depicted in **Table 1**. Encounter length did not significantly differ between ICAN and control
5 encounters.
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10 11 *3.1. Clinician reported feasibility of ICAN*

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13 Clinicians found the tool feasible to use in the majority of encounters. 62% reported it
14 very easy or easy, 32% reported it as neither easy nor difficult, and 5% reported it was difficult
15 to use in that encounter. There were two encounters where it was reported as difficult by
16 different clinicians. For one encounter the clinician stated, "Unfortunately, this made her
17 appointment go over by about 30 minutes. It was good we discussed issues with the portal [*an*
18 *online platform that allows patients to access their health information*] and her life and stressors
19 but it wasn't a big concern (why it wasn't a reason for the appointment) but we spent a good deal
20 of time on it." Upon further review of this video, it appears that the primary reason that the
21 encounter lasted substantially longer than planned was a lack of fidelity to ICAN training. After
22 the clinician asked the patient what stood out to her from ICAN, she continued to elicit
23 information about each burden listed by the patient, rather than connect the patient's response to
24 the remainder of the clinical visit. Addressing the two key issues the patient brought up, work
25 stress and being active, took approximately five and a half minutes in total. Following that, the
26 clinician spent an additional five and a half minutes reviewing the other items on the tool.
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45 In the second encounter, the clinician stated, "I enjoy the learning and conversation
46 obtained from form [*sic*] but didn't have the extra time in schedule [*sic*] necessary to address
47 each issue - easily added another 15-20 minutes to appointment." In this encounter, the patient
48 indicated that her emotional life was both a source of satisfaction and a burden. The clinician
49 enquired further and thus provided the patient with an opportunity to talk about her prolonged
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3 grief after the loss of her spouse and her concerns about possible depression. In response the
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5 clinician screened the patient for potential depression. Total time using the tool and discussing
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7 that issue took four minutes of the total visit. The patient was scheduled for a 45 minute general
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9 medical exam, and the total video recorded visit time was 26 minutes, which did not include the
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11 physical exam at the end of the encounter.
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14 15 16 *3.2. Survey Results*

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19 We did not find any items with significant differences between patients in either cohort
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21 for the consultation care measure (**Table 2**). When comparing patients and clinicians across the
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23 consultation care measure, among the items that overlapped, clinicians tended to score
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25 themselves poorer than patients. This was more prevalent when the ICAN tool was used (**Table**
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27 **3**).
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30 31 32 *3.3. Videographic Results*

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34 Issues discussed during clinical encounters did significantly differ between ICAN and
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36 control encounters in multiple domains (**Table 4**). Specifically, discussions about being active,
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38 diet, and taking medications were discussed significantly more frequently in ICAN encounters.
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40 Discussions about administrative treatment work, other treatment work, family, living
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42 arrangements, and comfort were discussed significantly less frequently in ICAN encounters. We
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44 noticed that often topics about family were used as conversation fillers in control encounters,
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46 whereas there may have been less room for this when patients were prompted to bring up issues
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48 that mattered most to them.
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52 53 54 **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

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3 patients in this setting and population (suburban, Midwest, academic medical center). However,
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5 these topics have been noted as important treatment burden factors for patients in other diverse
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7 samples; patients noted that they were aware their clinicians wanted them to eat healthier or
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9 exercise more frequently, but important barriers existed of which their clinicians were unaware.²⁵
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11 Furthermore, in a previous study of patient-clinician concordance, patients were more likely than
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13 clinicians to rank being active as one of their top three health concerns.²⁶ Future research should
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15 examine whether the topics discussed more often are different in other clinical settings (e.g. rural
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17 and urban), with different populations (e.g. unsalaried clinicians, underserved patients), and what
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19 clinicians can do in clinical encounters with this information.
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25 Ultimately, the discussion of topics of greater importance to patients and their competing
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27 priorities is important as it could lead to better tailoring of treatment plans to patients' context,
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29 improving patients' workload-capacity balance in managing chronic illness. As mentioned
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31 earlier, the Cumulative Complexity Model postulates that workload-capacity balance impacts
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33 patients' abilities to access and use healthcare and enact self-care, with downstream impact on
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35 their health outcomes.¹⁹ Furthermore, communication models, such as the one proposed by Street
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37 et al. have postulated the pathways from patient-clinician communication to patient outcomes.²⁷
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39 For example, Street's model illustrates that communication functions supported by ICAN such as
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41 managing uncertainty, fostering relationships, and enabling self-management can impact
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43 proximal outcomes such as patient trust and "feeling known," with downstream consequences on
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45 self-care skills, adherence, and ultimately health outcomes.²⁷ ICAN is a general discussion aid
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47 for use in chronic illness, intended to provide insight into the personal, social, material, and
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49 spiritual aspects of the patient's situation; it can be used in conjunction with the many available
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51 decision-specific conversation aids.²⁸ For example, an ICAN conversation may illuminate that a
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3 patient finds their overall medication regimen particularly burdensome, and this may spark a
4 treatment-specific conversation about choosing a different treatment in replacement of a current
5 one or inform the decision to add or not add another medication to the list. A good example of
6 the use of ICAN and a treatment decision aid is available on the web.²⁹ Used in this way,
7 clinicians may fully understand patients' competing priorities as well as treatment-specific
8 values and preferences, and therefore, be able to co-create with them treatment plans that fit their
9 context and allow them to lead quality lives to the fullest extent.
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20 Examining the two encounters noted as difficult for clinicians yielded important
21 information about ICAN implementation challenges. The encounter where additional time was
22 used to discuss all ICAN items suggests that additional training may be needed for clinicians to
23 illustrate how to connect the initial question of “What stands out to you?” to the clinical reason
24 for the appointment, and how to continue the use of the discussion aid at future encounters. In
25 the encounter in which the patient was able to discuss potential concerns of depression, the
26 clinician noted that this added an additional 15 – 20 minutes to the encounter, whereas the actual
27 discussion took less than five minutes. The perceived duration may have felt longer than the
28 actual duration because of the heavy nature of the topic discussed. Past research in primary care
29 patients with multi-morbidity has shown that clinician comfort level with these types of difficult
30 topics is low and that in practicing a traditional “additive-sequential model,” where each problem
31 is treated independently and prioritized, these issues may never get acknowledged.^{15,30} Therefore,
32 the implementation of ICAN can provide an opportunity to train clinicians to address potentially
33 difficult topics, manage their expectations of those discussions, and learn how to successfully
34 have those conversations. Specifically, this requires attention and clinician exposure in future
35 ICAN trainings to the potentially uncomfortable and off-script conversations that may occur as a
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3 result of using the aid, as well as practice in having those conversations first in safe spaces, such
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5 as with peers and trainers, prior to real-life clinical encounters.
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8 9 *4.5. Conclusion*

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11 In conclusion, we successfully pilot tested the ICAN Discussion Aid in primary care
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13 encounters. This study illustrated that ICAN was perceived as feasible to implement in normal
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15 clinical practice, did not impact visit length, and impacted the conversation topics discussed in
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17 encounters. While patients perceived improved visit success with ICAN use, clinicians perceived
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19 worsened visit success. Clinical encounters that were noted as difficult to use ICAN point to
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21 additional ICAN training needs in future implementation and study settings. ICAN deserves
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23 further testing to determine if its implementation leads to better workload-capacity balance for
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25 patients living with chronic illness and if this translates to improved patient health outcomes.
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30 31 *Authors' contributions*

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34 KRB was responsible for study design, overall study execution, analysis, and the draft
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36 manuscript. CCD and AT conducted videographic analysis and provided critical revisions for the
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38 manuscript. MB and RG conducted statistical analysis, created tables, and drafted the statistical
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40 sections of the manuscript. EB was responsible for study coordination of the study and data
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42 collection procedures. PO assisted with data cleaning procedures, drafting of the manuscript, and
43
44 critical revisions to the manuscript. SVA served as clinical champion for the study and provided
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46 critical revisions to the manuscript. KS provided revisions to the manuscript and data
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48 visualization. VMM assisted KRB with study design and oversight of the project.
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52 53 *Conflicts of Interests*

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3 The authors of this manuscript have no conflicts of interests to report.
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8
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10
11 Arlene Kogod Center for Aging.
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15 *Data Availability*
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18 Patients in this study provided informed consent regarding the use of their de-identified data
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20 beyond the proposed study. De-identified data from participants that consented to future use of
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22 their data is available upon request from investigators in the Knowledge and Evaluation
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24 Research Unit.
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28 *Included Figures*
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31 Figure 1: ICAN Discussion Aid
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35 Figure 2: Detailed Enrollment Information
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	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)	

27 [^]All enrolled patients.

28 *3 patients in intervention missing data on characteristics.

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36 **Table 2: CCM Patient Scores**

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	ICAN (N=42)	Pre-Intervention (N=39)	Total (N=81)
Overall score			
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)	

47 *Adjusted by clinician clustering; lower scores = better

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For peer review only

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.

	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

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- What are you doing when you're not sitting here with me?
- Where do you find the most joy in your life?
- What's on your mind today?

These questions can help shift discussion towards the broader life of your patient. Use as many of them as you wish.

Are these areas of your life a source of satisfaction, burden, or both?

	Satisfaction	Burden
My family and friends	<input type="checkbox"/>	<input type="checkbox"/>
My work	<input type="checkbox"/>	<input type="checkbox"/>
Free time, relaxation, fun	<input type="checkbox"/>	<input type="checkbox"/>
Faith or personal meaning	<input type="checkbox"/>	<input type="checkbox"/>
Where I live	<input type="checkbox"/>	<input type="checkbox"/>
Getting out and transportation	<input type="checkbox"/>	<input type="checkbox"/>
Being active	<input type="checkbox"/>	<input type="checkbox"/>
My rest and comfort	<input type="checkbox"/>	<input type="checkbox"/>
My emotional life	<input type="checkbox"/>	<input type="checkbox"/>
My senses and memory	<input type="checkbox"/>	<input type="checkbox"/>
Eating well	<input type="checkbox"/>	<input type="checkbox"/>

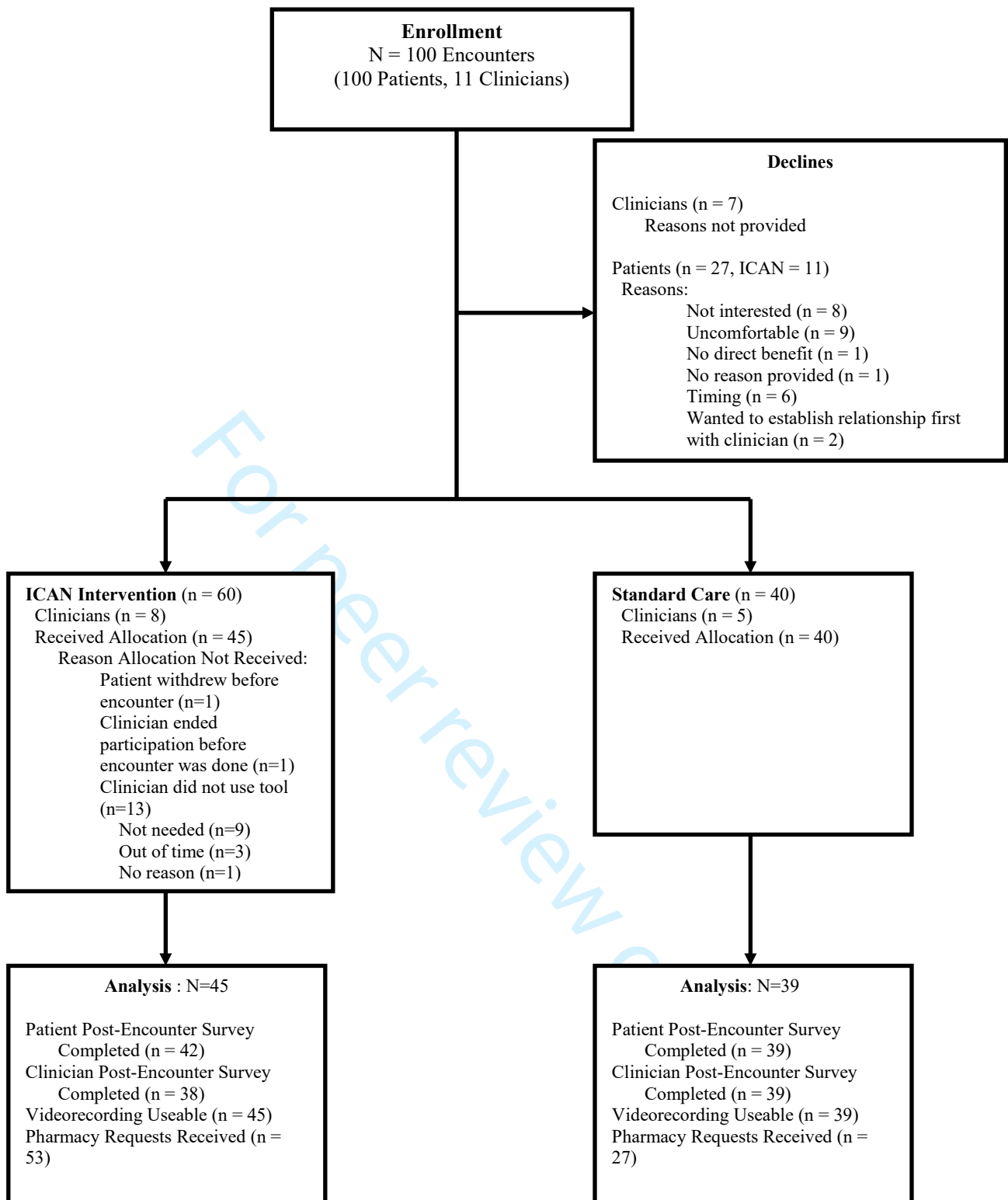
What are the things that your doctors or clinic have asked you to do to care for your health?

Do you feel that they are a help, a burden, or both?

	Help	Burden
<i>example: come in for appointments</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>example: take aspirin</i>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>



Figure 1: ICAN Discussion Aid
419x215mm (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	
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	Hydrochlorothiazide
	Hydrochlorothiazide
	Metolazone
Fibric acid	Fenofibrate
	Fenofibrate Micronized
Janus kinase (JAK) inhibitors	Xeljanz
Leukotriene receptor antagonists	Montelukast Sodium
Loop diuretic	Furobemide
	Furosemide
	Torseamide
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	Spirolactone
SNRI	Desvenlafaxine ER
	Duloxetine DR
	Duloxetine HCL
	Duloxetine Hcl
	ER Venlafaxine
	Escitalopram Oxalate
	Venlafaxine XR
	Venlafaxin XR
	Venlafaxine ER
	Venlafaxine HCL ER
SSRI	Citalopram
	Citalpram
	Fluoxetine
	Fluoxetine HCL
	Paroxetine
	Paroxetine HCL
Selective estrogen receptor modulator (SERM)	Raloxifene HCL
	Tamoxifen
	Atorvastatin
Statin	Atorvastatin Calcium
	Locastatin
	Lovastatin
	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
	Cyclovenzaprine HCL
	Cyclovenzaprine HCL
	Nortriptyline
	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.