**Complete Title:** Enhancing patient ability to understand and utilize complex information concerning medication self-management

**Short Title:** Patient ability to understand medication self-management information

**NCT Number:** 02820038

**Drug or Device Name(s):** Not applicable

**FDA IND/IDE (if applicable):** Not applicable

**Sponsor:** The University of North Carolina at Chapel Hill

**Protocol Date:** September 24, 2019

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**PROTOCOL TITLE:** Enhancing patient ability to understand and utilize complex information concerning medication self-management

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Lead Investigator:

Susan J. Blalock, PhD

University of North Carolina at Chapel Hill

Protocol Version: 1.0

Version Date: September 24, 2019

I confirm that I have read this protocol and understand it.

Principal Investigator Name: Susan J. Blalock, PhD

Principal Investigator Signature: Susan J. Blalock

Date: September 24, 2019

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## ABBREVIATIONS AND DEFINITIONS OF TERMS

| Abbreviation | Definition |
|---|---|
| API | Application Programming Interface |
| PPRN | Patient-powered research network |
| CDWH | Carolina Data Warehouse for Health |
| CMI | Consumer medication information |
| DMARDS | Disease modifying antirheumatic drugs |
| FTT | Fuzzy Trace Theory |
| GHLF | Global Healthy Living Foundation |
| Neuro-QOL | Quality of Life in Neurological Disorders |
| NVS | Newest Vital Sign |
| PC-SAS | Statistical Analysis Software for personal computer |
| RA | Rheumatoid arthritis |
| RAPID3 | Routine Assessment of Patient Index Data Version 3 |
| REDCap | Research Electronic Data Capture |
| SMART | Strategic Memory Advanced Reasoning Training |
| TOSL | Test of Strategic Learning |
| TSQM | Treatment Satisfaction Questionnaire for Medication |
| VSL | Visual Selective Learning |

PROTOCOL SYNOPSIS

| | |
|---|---|
| Study Title | Enhancing patient ability to understand and utilize complex information concerning medication self-management |
| Funder | Patient-Centered Outcomes Research Institute |
| Clinical Phase | Not Applicable |
| Study Rationale | Rheumatoid arthritis is a systemic, autoimmune disorder. Current guidelines underscore the importance of aggressive treatment with disease modifying antirheumatic drugs (DMARDS) to control inflammation. A major issue in implementing aggressive therapy in practice, however, involves patient reluctance to escalate therapy when they believe that their symptoms are tolerable, despite the presence of active disease, due to concerns about medications risks. Moreover, patients often find it difficult to obtain accurate and personally-relevant information about medication risks and benefits that is written in language they can understand. There is a clear gap between the information patients want about medication risks and benefits and the information they currently receive as part of routine care. |
| Study Objective(s) | The aim of the proposed project is to compare the effectiveness of two strategies designed to enhance patient understanding of medication risks/benefits: (1) Medication Guides, mandated for many medications by the Food and Drug Administration and (2) DrugFactsBoxes®, developed by Woloshin and Schwartz to enhance the usability of consumer medication information. The investigators will also assess whether the effectiveness of these communication strategies can be increased by Gist Reasoning Training, which is designed to enhance patients' ability to extract meaningful gist from complex information. |
| Test Article(s)<br>*(If Applicable)* | Two interventions will be evaluated.<br>**DrugFactBoxes®** are written summaries of information concerning medication risks/benefits that follow plain language guidelines and best practices to enhance comprehension among individuals with limited literacy or numeracy skills.<br>**Gist Reasoning Training delivered via the SMART Program** is a patient education program designed to help people develop the cognitive skills needed to abstract meaning from complex written material. The cognitive skills trained include: selective attention to important information, integrating information, and evaluating the information from different perspectives. |

| | |
|---|---|
| Study Design | The study will use a randomized controlled trial design, with four study arms. Data will be collected primarily via telephone interviews, and self-administered, Internet-based surveys using REDCap and Qualtrics. All participants will be followed for 6 months after the completion of baseline data collection. |
| Subject Population<br>key criteria for Inclusion and Exclusion: | Inclusion Criteria<br>1. Subjects age 18 years and older<br>2. Subjects with physician-confirmed rheumatoid arthritis or similar type of inflammatory arthritis<br>Exclusion Criteria<br>1. Subjects who do not speak English<br>2. Subjects who do not have access to the internet and a working email address<br>3. Subjects who are not eligible for DMARD therapy<br>4. Subjects who have health problems (e.g., active cancer, planned surgery) that prevent changes in their medication regimen |
| Number Of Subjects | The targeted sample size is 300. |
| Study Duration | Each subject's participation will last 6 months.<br>The entire study is expected to last 3 years. |
| Study Phases<br>Screening<br>Study Treatment<br>Follow-Up | (1) Screening: screening for eligibility and obtaining consent<br>(2) Baseline data collection: Telephone interview and internet-based self-administered questionnaire<br>(3) Intervention delivery: Given access to written medication information immediately following baseline. Completion of SMART training usually requires one to three months<br>(4) Follow-Up data collection: Three follow-ups, conducted 6 weeks, 3 months, and 6 months following completion of baseline data collection |
| Efficacy Evaluations | The primary outcome variable is informed decision making regarding use of DMARDs. Participants will be classified as meeting the criteria for informed decision making if they: (1) have adequate knowledge, have values that favor use of medications to control disease activity, and are using a DMARD **OR** (2) Have adequate knowledge, have values indicating reluctance to use medications to control disease activity, and are not using a DMARD. All other individuals will be classified as not meeting the criteria for informed decision-making. |

| | |
|---|---|
| Pharmacokinetic Evaluations | Not applicable |
| Safety Evaluations | Not applicable |
| Statistical And Analytic Plan | Using an intention-to-treat approach, the investigators will use logistic regression to test three hypotheses in primary analyses, with alpha (2-tailed) set at 0.05.<br>1. Participants will be more likely to meet the criteria for Informed Decision-Making at the 6-month follow-up if they were assigned to receive written medication information via the DrugFactsBox® format compared to the Other CMI format.<br>2. Participants will be more likely to meet the criteria for Informed Decision-Making at the 6-month follow-up if they were assigned to receive gist reasoning training, delivered via the SMART Program, compared to those who were not assigned to receive this training.<br>3. Participants will be more likely to meet the criteria for Informed Decision-Making at the 6-month follow-up if they were assigned to receive medication information via the DrugFactsBox® format **combined with** gist reasoning training, delivered via the SMART Program, compared to individuals in the other three groups. |
| DATA AND SAFETY MONITORING PLAN | The principal investigator will have primary responsibility for data quality management and ongoing assessment of safety. The principal investigator will work closely with clinical co-investigators to assess safety concerns. Because this project is associated with minimal risk, the investigators have not incorporated a formal Data and Safety Monitoring Board. |

# 1 BACKGROUND AND RATIONALE

## 1.1 Introduction

Rheumatoid arthritis (RA) is a systemic, autoimmune disorder affecting 0.5% to 1% of the adult population in developed countries worldwide. Current guidelines underscore the importance of aggressive treatment of RA with disease modifying antirheumatic drugs (DMARDS) to control inflammation. Aggressive treatment has been shown to improve patient-centered outcomes, including better symptom control, functional status, and health-related quality of life and reduce the risk of premature death. A major issue in implementing aggressive therapy in practice, however, involves patient reluctance to escalate therapy when they believe that their symptoms are tolerable, despite the presence of active disease, due to concerns about medications risks. Moreover, patients often find it difficult to obtain accurate and personally-relevant information about medication risks and benefits that is written in language they can understand. There is a clear gap between the information patients want about medication risks and benefits and the information they currently receive as part of routine care.

## 1.2 Name and Description of Investigational Product or Intervention

**DrugFactBoxes®** are written summaries of information concerning medication risks/benefits that follow plain language guidelines and best practices to enhance comprehension among individuals with limited literacy or numeracy skills.

**Gist Reasoning Training delivered via the SMART Program** is a patient education program designed to help people develop the cognitive skills needed to abstract meaning from complex written material. The cognitive skills trained include: selective attention to important information, integrating information, and evaluating the information from different perspectives.

## 1.3 Non-Clinical and Clinical Study Findings

The main potential risk associated with the study involves breach of confidentiality. Because the investigators are collecting information concerning patient health status and medication use, it is possible that a breach of confidentiality could affect participants' ability to obtain health insurance.

The investigators anticipate that all study participants have the potential to benefit from study participation by receiving information concerning the risks and benefits associated with different RA treatment options. Patients report having difficulty obtaining this type of information. The investigators expect participants assigned to the DrugFactsBox® group combined with Gist Reasoning Training to derive the greatest benefit. In addition,

the investigators will offer all participants an opportunity to take part in the on-line BetterChoices/BetterHealth® Program free of charge. Thus, participants have the potential to benefit from participation in this chronic illness self-management program as well.

### 1.4 Relevant Literature and Data

Rheumatoid arthritis (RA) is a systemic, autoimmune disorder affecting nearly 1% of the adult population.[1] The prevalence of RA is about two times higher in females than males.[2] As part of the disease process, chronic synovial inflammation and hyperplasia cause joint destruction and bone erosion,[3] manifesting itself to patients through pain, fatigue, and functional impairment.[4] Despite advances in therapy, RA often leads to progressive joint destruction, affecting patients' ability to work and perform social roles.[5] The systemic inflammation associated with RA can also damage internal organs, including the heart and lungs, leading to premature death.[6,7] Depression is common among patients with RA, affecting between 13-20% of patients.[8] It has recently been recognized that cognitive impairment is also more common among individuals with RA.[9] Thus, although the word "arthritis" may bring to mind the image of a disease that affects only the joints, the impact of RA on patients and their families extends much further, potentially affecting every aspect of life.

Current therapeutic guidelines underscore the importance of aggressive treatment of RA with disease modifying antirheumatic drugs (DMARDS) to control inflammation.[10] Aggressive treatment has been shown to improve patient-centered outcomes, including better symptom control, functional status, and health-related quality of life and reduced risk of premature death.[11-13] For example, a prospective cohort study involving over 1,200 RA patients found a 70% reduction in the risk of cardiovascular death among patients using methotrexate (a DMARD) compared to those not using a DMARD.[13] Current guidelines endorse a treat-to-target strategy, with achieving a clinical remission as the primary target and emphasize the role of patients in shared decision making.[10] A major issue in implementing treat-to-target principles in practice, however, involves patient reluctance to escalate therapy when they believe that their symptoms are tolerable, despite the presence of active disease.[14-16] Across seven studies, the median adherence rate to DMARDs assessed using objective measures (e.g., electronic devices in medication caps to track usage, records from prescription claims databases) was 67% (range 22%-107%).[17] Another review of 11 studies conducted in the US found that among those who initiated biologic therapy, only 38% to 56% were still using a biologic 12 months following initiation.[18] Thus, adherence and persistence with DMARD therapy is often suboptimal and uncontrolled inflammation places patients at increased risk for the types of health problems described previously (e.g., cardiovascular disease).

Patient reluctance to use DMARDS when they believe their symptoms are tolerable is understandable because the potential benefits associated with these medications are accompanied by concerns about serious risks.[19-22] Moreover, obtaining accurate and personally-relevant information about medication risks is challenging. Previous research suggests that, although most RA patients want information about medication risks, many have a poor understanding of these risks.[23-25] In some ways, this is not surprising. A study conducted by our research team found that rheumatologists provide relatively little information about medication risks during routine patient office visits.[26] In that study, the investigators analyzed over 1,000 transcripts of patient office visits and observed relatively little discussion of medication risks. For example, in visits where the rheumatologist proposed adding a biologic DMARD to the patient's medication regimen, risks associated with immune system suppression were discussed only 48.5% of the time. In visits where the rheumatologist suggested adding methotrexate, the risk of liver toxicity was discussed only 15.1% of the time. Other risks were discussed even less often. The investigators used the same transcripts to examine the clarity of the risk-benefit communication that occurred during the visit.[27] Four patients with RA coded the transcripts with respect to the gist that rheumatologists conveyed concerning medication safety, effectiveness, and need.[27] In 29% of the transcripts coded, the patient-coders indicated that it was not clear if the rheumatologist was concerned about medication safety. In 14% of the transcripts, the patient-coders could not tell whether the rheumatologist thought a medication was helping and/or was needed. In another study conducted by our research team, over 80% of arthritis patients reported receiving conflicting information about their medications and the most commonly reported area of conflict involved medication risks.[28]

Although the FDA requires that patients receive a Medication Guide with most DMARDs, research in other patient populations suggests that many patients have difficulty understanding the information contained in Medication Guides.[29-35] These findings highlight the gap between the information patients want about medication risks and benefits and the information they currently receive as part of routine care. Together, the findings reported above support a simple and straight-forward conclusion: The strategies currently used to inform RA patients about treatment risks and benefits are not working.

As described above, many patients struggle to find the right balance between wanting to keep their illness under control and wanting to avoid unnecessary risks. It is also important to recognize that medication safety is not just a function of medication properties alone. It is also a function of how medications are used. For example, medications are "safer" when patients understand and follow recommended safety precautions (e.g., avoiding alcohol when taking methotrexate, obtaining routine blood tests to monitor liver and kidney function). Because most patients self-manage their medications, safe medication use requires that patients understand: the nature of

potential adverse effects, how to monitor therapy to detect potential problems early, safety precautions to follow to reduce risk, and what to do if adverse effects occur.[36,37] The complexity of this information, in addition to information about alternative treatment options with different risk/benefit profiles, can easily overwhelm patients' coping ability and interfere with optimal decision making. Health literacy/numeracy deficits can compound this problem. It is widely recognized that millions of Americans lack the health literacy and numeracy skills needed to be able to understand health-related information and that lack of these skills can lead to poor health outcomes.[38] Emphasizing the severity of this problem, one objective within the area of Health Communication and Health Information Technology in Healthy People 2020 is to increase patient health literacy skills.[39] Although many studies have been conducted to determine how design features (e.g., use of headers) affect patient ability to understand and use written health information, few studies have examined interventions designed to increase patient health literacy/numeracy skills.[38]

This study was based on the premise that interventions designed to educate patients about the risks/benefits associated with different therapeutic options and medication self-management require a 2-pronged approach: simplifying material to convey the essential gist of information and helping patients develop the health literacy/numeracy skills needed to process information concerning complex issues (e.g., scientific uncertainty). The DrugFactsBox® format for presenting medication information was designed to address the first issue. The SMART Program was designed to address the second issue.

The study was informed by fuzzy-trace theory (FTT) a dual-process model of memory, reasoning, judgment, and decision making that has been used to study how people across the life span make decisions that involve risk.[40,41] Briefly, FTT posits that, when an individual is exposed to any meaningful stimulus (e.g., written prescription drug information), two types of representations of the stimulus are encoded in memory, a verbatim representation and one or more gist representations. Verbatim representations capture the exact words, numbers, or images included in the stimulus, whereas gist representations capture the essential, bottom-line meaning of the stimulus to the person, including its emotional meaning. Basic research has demonstrated that gist representations are retained longer in memory and are more easily retrieved from memory than verbatim representations, making them more accessible when individuals are making judgments and decisions.[42,43]

A central tenet of FTT is that the ability to extract meaningful gist from complex information is essential for informed decision making. Gist reasoning requires one to "connect the dots" between separate pieces of information, rather than processing individual facts in isolation.[44] Substantial empirical research has confirmed the FTT prediction that the ability to extract meaningful gist from information increases with

development (i.e., as children grow to adulthood) and the acquisition of expertise in a specific domain.[45-49]

Using FTT as our theoretical framework, the aim of this study was to evaluate the effectiveness of two interventions designed to enhance patient understanding of medication risks/benefits: the DrugFactsBox® format for presenting written medication information and the SMART Program to enhance gist reasoning ability. As shown in Figure 1, the investigators hypothesized that both interventions would increase: (1) patient knowledge concerning medication risks/benefits and (2) interest in obtaining additional information about illness self-management. Moreover, by improving gist reasoning ability, the investigators hypothesized that the SMART Program would work synergistically with the Drug Facts Boxes to improve patient health outcomes. Our primary outcome variable was informed decision-making, defined as making a value-consistent decision concerning DMARD use in the presence of adequate knowledge. Other intermediate and distal outcome variables are shown in Figure 1.

# 2 STUDY OBJECTIVE

## 2.1 Primary Objective

The aim of the proposed project is to compare the effectiveness of two strategies designed to enhance patient understanding of medication risks/benefits: (1) Medication Guides, mandated for many medications by the Food and Drug Administration and (2) DrugFactsBoxes®, developed by Woloshin and Schwartz to enhance the usability of consumer medication information. The investigators will also assess whether the effectiveness of these communication strategies can be increased by Gist Reasoning Training, which is designed to enhance patients' ability to extract meaningful gist from complex information.

# 3 INVESTIGATIONAL PLAN (brief overview)

## 3.1 Study Design

The study will use a randomized controlled trial design, with four study arms. Data will be collected primarily via telephone interviews, and self-administered, Internet-based surveys using REDCap and Qualtrics. All participants will be followed for 6 months after the completion of baseline data collection.

## 3.2 Allocation to Treatment Groups and Blinding (if applicable)

Participants will be randomized to study arm on a 1:1:1:1 basis. Prior to the start of participant recruitment, the principal investigator will generate a random allocation sequence using PC-SAS® (version 9.4). Random numbers will be generated in blocks of 20 to ensure balance across the four study groups over the entire course of data collection. The random number sequence will be imported into the REDCap tracking

database used by the project director, working out of the UNC-Chapel Hill office, to record the name and contact information for study participants as they are enrolled in the study. To ensure allocation concealment, the REDCap database will be programed so that the group assignment variable: (1) cannot be viewed until after the patient contact information has been entered and (2) cannot be changed after the patient contact information has been entered. All personnel involved in data collection and delivery of the SMART program were blinded to participant group assignment.

### 3.3 Study Duration, Enrollment and Number of Subjects

The study has a targeted sample size of 300. There are four data collection points, baseline and 6 weeks, 3 months and 6 months following baseline.

The investigators will recruit 300 adults (age 18+) with physician-confirmed RA to participate in the study using a multi-pronged recruitment strategy. First, patients will be recruited from rheumatology clinics at four large academic medical centers: the University of North Carolina at Chapel Hill; the University of Alabama at Birmingham; the University of Texas Southwestern Medical Center located in Dallas, Texas; and the University of Pittsburgh Medical Center. A clinical coordinator who is a regular clinic staff member or a member of the research staff (working under the supervision of a clinic staff member) will review the clinic schedule to identify potential participants prior to their visit. The clinical coordinator or research staff member will then approach the potential participant when they arrive for their visit.

Second, because the investigators do not want to restrict study participation to patients cared for by a rheumatologist, they are partnering with the Global Healthy Living Foundation (GHLF) to recruit participants through Creaky Joints and the Patient-Powered Research Network (PPRN) they have established, AR-PoWER. Creaky Joints is an online arthritis patient support community with over 5,000 members. The AR-PoWER Network has over 4,000 members with most members reporting having RA. GHLF will post a notice pertaining to the study on the “Opportunities Central” portion of the AR-Power Network website and will email members of both Creaky Joints and the AR-Power Network to inform them about the study. They will also use social media such as Twitter to raise awareness of the study. Individuals with interest in participating in the study will be instructed to contact the project director at UNC-CH by phone or email.

In efforts to expand recruitment, the investigators have created a study Twitter (@medigiststudy) and Facebook page (What's the Gist? About Rheumatoid Arthritis), and updated the Study Website (medigist@web.unc.edu). The investigators plan to raise awareness about the study via these social media and website outlets. Individuals with interest in participating in the study will be instructed to contact study personnel at UNC-CH by phone or email.

The investigators will use the Carolina Data Warehouse for Health (CDWH) to identify minority RA patients in the UNC Healthcare System. The investigators will mail recruitment letters to patients identified via the CDWH describing the study, and providing contact information of study personnel to those that are interested in participating.

### 3.4 Study Population

The investigators will recruit adults (age 18+) with physician-confirmed RA to participate in the study. Individuals who do not speak English will also be excluded because it would be difficult, due to budgetary considerations, to deliver the SMART Program in languages other than English. Individuals will be excluded if they do not have access to the Internet and a working email address because the SMART Program can only be administered online, and many of the secondary outcome measures will be administered online, it is important that participants have Internet access. Participants will also be excluded if they are not eligible for DMARD therapy. In addition, individuals will be excluded if they have any health problems that prevent changes in their medication regimen.

## 4 STUDY PROCEDURES (what will be done)

### 4.1 Screening/Baseline Visit procedures

At clinic sites, recruitment procedures will be implemented either by a clinical coordinator who is a regular member of the clinic staff or a research staff member working under the supervision of a clinic staff member. For participants recruited via the AR-POWER network or Creaky Joints, a research staff member will implement recruitment procedures.

Potential participants will be interviewed to assess eligibility. Eligible participants will complete a telephone interview and a baseline questionnaire delivered via the Internet using Qualtrics and REDCap. The telephone interview will ask the participant knowledge questions about RA and will assess their health literacy via the standardized Newest Vital Signs instrument. The baseline questionnaire will include a list of DMARDS currently available in the US for the treatment of RA. Participants will be asked to indicate the ones that they are currently using.

4.2 **Intervention/Treatment procedures (by visits)**

After participants complete the baseline questionnaire, they will be randomly assigned to one of four study groups: Other CMI without Gist Reasoning Training, Other CMI with Gist Reasoning Training, DrugFactsBox® without Gist Reasoning Training, and DrugFactsBox® with Gist Reasoning Training. Note that in most cases the "Other CMI" provided will be FDA approved Medication Guides. However, not all DMARDS are required to have a Medication Guide. In these cases, the investigators will provide CMI developed by the American Society of Health-System Pharmacists®. These materials are similar to the CMI that is given to patients in the United States when prescriptions are dispensed.

Participants will then be directed to a website that provides written prescription drug information (either Other CMI or DrugFactsBoxes®, depending on group assignment) for the medications they are currently using. The website will allow participants to print a hard copy of the materials, if desired. The website will also allow them to access information about other DMARDs. For participants randomized to the gist training group (SMART Program), staff at the Center for BrainHealth at the University of Texas-Dallas will contact participants, either by email or by phone, to enroll them in the next SMART Program. The training program will be delivered in small groups of 5-6 individuals over a 1-month period. Each program will include 4 60-minute sessions delivered by research personnel certified to provide the program. Training will be presented via an online video conferencing platform, such a BlueJeans®, that permits synchronous, audio and visual communication between trainers and participants. Participants only need a computer (desk, laptop, tablet) or mobile phone with internet access to participate.

**4.3 Follow- up procedures (by visits)**

Follow-up data will be collected 6-weeks, 3-months and 6-months after baseline. After the 6-week follow-up interview, all participants will be sent a letter that gives them the opportunity to participate in the online Better Choices, Better Health® program free of charge. This program is adapted from the Arthritis Self-Management Course developed by Lorig and colleagues. In the proposed study, the investigators will use participant acceptance of the offer to participate in the Better Choices, Better Health® program as a behavioral measure of patient interest in obtaining additional information about RA self-management and alternative treatment options.

4.4 **Unscheduled visits**

Not applicable

### 4.5 Concomitant Medication documentation

Not applicable

### 4.6 Rescue medication administration ( if applicable)

Not applicable

### 4.7 Subject Completion/ Withdrawal procedures

The interventions tested involve minimal risk. Therefore, the investigators do not plan to withdraw individual participants for any reason. However, if a participant becomes upset concerning any study procedures, the investigators will ensure that they understand that they have the right to withdraw from the study at any time, without penalty. When participants express a desire to withdraw from the study, the investigators will solicit their reasons for withdrawing and document the reasons given.

### 4.8 Screen failure procedures

Individuals who were screened for study eligibility, but who did not meet the eligibility criteria, will be thanked for their interest in the study.

## 5 STUDY EVALUATIONS AND MEASUREMENTS (how measurements will be made)

### 5.1 Efficacy Evaluation (if applicable)

Efficacy data will be collected via a combination of telephone interviews and self-administered questionnaires, completed via REDCap. Measures included in the interviews and questionnaires are described below and summarized in Table 1.

**Primary Outcome:** The primary outcome variable for this study is Informed Decision-Making. Informed Decision-Making is typically conceptualized as making a decision, based on adequate knowledge, that is consistent with one's values.[50-53] To operationalize this definition, the investigators will assess three variables: knowledge of RA and RA treatment options, values pertaining to the management of RA, and current DMARD use.

**Knowledge** will be assessed by three separate instruments administered via telephone interview: an 8-item measure developed by Fayet and colleagues[54] that assesses knowledge concerning methotrexate, which is often first-line therapy for RA; a 20-item measure developed by Fraenkel and colleagues[55] to assess knowledge concerning biologic treatment options; and an 8-item measure developed by Barton and colleagues[56] that assesses knowledge of RA and RA treatment options more generally.

**Values.** Questions included in the self-administered questionnaires will ask participants to indicate the extent to which they agree or disagree with 10 simple values statements (e.g., It is OK to ignore the risk of a serious side effect if it is extremely rare; It is better to

continue with the pain I know than to change my medications) developed by Fraenkel and colleagues.[57,58] Responses will be recorded on a 4-point scale ranging from 1=*Strongly Agree* to 4=*Strongly Disagree*. Responses will be summed and rescored to yield a composite scale that ranges from -15 to +15, where positive numbers reflect values favoring the use of medications to control RA disease activity.

**DMARD Usage** will be assessed via the online questionnaires. Participants will be shown a checklist of 19 medications used to treat RA (abatacept, adalimumab, azathioprine, certolizumab pegol, cyclosporine, etanercept, golimumab, gold, hydroxycholoroquine, infliximab, leflunomide, methotrexate pill, methotrexate shot, minocycline, rituximab, sulfasalazine, tocilizumab infusion, tocilizumab shot, and tofacitinib) and asked to check all of those that they are currently using. Participants will also be to check an option labeled *None of the above*. DMARD Usage will be scored as "0" if the participant reports using no DMARDS and "1" if the participant reports using one or more DMARDS.

**Informed Decision-Making.** Participants will be classified as meeting the criteria for informed decision making if they:

(1) Answer at least 85% of the knowledge items correctly, score greater than 0 on the values scale indicating favorable attitudes concerning the use of medications to control disease activity, and are using a DMARD **OR**

(2) Answer at least 85% of the knowledge items correctly, score 0 or less on the values scale indicating reluctance to use medications to control disease activity, and are not currently using a DMARD.

Individuals who fail to meet either set of criteria will be classified as not meeting the criteria for informed decision-making.

**Proximal Secondary Outcomes:** The investigators will assess five proximal secondary outcomes: Gist Reasoning Ability; Selective Learning; Information Seeking; and two specific types of knowledge, Verbatim Recall and Medication Self-Management Knowledge. These variables, which are described below, are considered proximal because the investigators conceptualize them as direct effects of the intervention.

**Gist Reasoning Ability**, also referred to as integrated reasoning, will be assessed by the Test of Strategic Learning (TOSL). The TOSL was developed by Chapman and colleagues to systematically quantify participants' capacity to synthesize and interpret high-level meaning from lengthy multi-faceted textual information.[59,60] The TOSL consists of four text passages of similar length and complexity. At each data collection point, participants will read one of the text passages presented via an online learning platform. (The texts, as well as their order of presentation, will be randomized at each assessment so that participants will not see the same text twice.) Participants will not be allowed to return to the passage once they finished reading. After reading the passage,

participants will be asked to provide a synthesized, condensed version of the text in their own words, conveying primarily high-level ideas of substance rather than specific details. They will be given five minutes to complete this task. Participants will then be asked to generate as many interpretations (i.e., lessons learned) as possible that could be derived from the passage. They will be given three minutes to complete this task.

Responses will be scored using a manualized, objective scoring system by a trained and experienced rater, based at the Center for BrainHealth, who is blinded to participants' group assignment and time point of testing. Two separate scores will be derived from participant responses: number of abstracted ideas (Complex Abstraction) and a weighted index reflecting the quantity and quality of high-level interpretations (Lesson Quality). High-level interpretations will be judged against a rubric based on the specific content of each passage.

**Selective Learning** is defined as the ability to optimize processing of incoming information by controlling working memory to try to remember high value information while inhibiting low value information.[61] To assess this ability, the Visual Selective Learning (VSL) task will be administered as part of each telephone interview by showing participants 3 lists of 16 words via a PowerPoint presentation imbedded in a YouTube video. Each word will appear on a separate screen for 1 second. Half of the words will be in uppercase and half will be in lowercase. In some trials, participants will be instructed that uppercase words are valued at 10 points and lowercase words at 1 point; in other trials, the point value was the opposite. Participants will be told to remember as many words as they could, but that their goal is to earn as many points as possible. Different word lists will be used at each time point and the lists will be balanced across participants over the course of the study using procedures parallel to those for the TOSL. At each time point, scores will be summed across the three lists, yielding a composite score with a possible range from 0 to 264.

**Information Seeking** will be assessed using two behavioral measures incorporated into the design of the study. First, the investigators will create a website that provides easy access to information about RA, treatment options, and self-management strategies. The investigators will refer to this website at the RA Self-Management Website. Participants will be emailed a link to this website immediately after completion of 6-week follow-up data collection. The investigators will use Google analytics to track whether participants accessed the website and the specific website pages viewed. Second, immediately after completion of 6-week follow-up data collection, the investigators will email all participants an invitation to take part in BetterChoices, BetterHealth®, an online chronic illness self-management program, free of charge. The investigators will track whether or not participants enroll in the class, the number of class sessions attended, and whether or not participants complete the class.

**Verbatim Recall** of information concerning potential medication benefits and harms will be assessed by medication-specific items developed specifically for this study. For each medication, the investigators will identify one potential benefit and one potential harm listed in the Drug Facts Box. Each question will ask participants about the probability of benefit/harm using a multiple-choice response format. To minimize response burden, participants will be asked these questions in relation to only one of their current RA medications. For participants taking more than one RA medication, the investigators will ask the items in relation to methotrexate, if methotrexate is being used. Otherwise, the investigators will ask the items in relation to the most commonly used biologic medication the participant is using or, in cases where the participant is not using any biologic medications, the investigators will ask the items in relation to a non-biologic medication. Correct responses will be summed across the benefit and harm items to yield a score ranging from 0 to 2. This measure will be administered, by telephone interview, only at the 6-week follow-up.

**Medication Self-Management Knowledge** will be assessed using a 45-item medication-specific measure tailored to the medications each participant reports using and developed specifically for this study. For participants using methotrexate, the items will focus on this medication. For participants not using methotrexate but using a biologic, the items will focus on the most commonly used biologic. Otherwise, the items will focus on a non-biologic. The first 42 items will involve a list of possible medication side-effects, some that are known risks for the targeted medication and some that are not. For each side-effect, participants will be asked whether or not they would call the doctor immediately if they experienced the side-effect. (Consumer medication information (CMI) typically includes information concerning those side-effects that require immediate medical attention.) The final three questions will be scenario-based and designed to assess knowledge of other aspects of medication use (e.g., whether medication should be stored in the refrigerator, what to do if medication is accidentally frozen, whether it is OK to get a flu shot when taking the medication). These questions will draw on information found in the medication information provided to participants. Correct answers will be summed across the 45 items and then transformed to a 100 point scale, reflecting the percentage of questions answered correctly.

**Intermediate Secondary Outcomes:** The investigators will assess three intermediate secondary outcomes: Treatment Satisfaction, Satisfaction with Medication Information, and Arthritis Self-Efficacy

**Treatment Satisfaction** will be assessed by the 9-item abbreviated Treatment Satisfaction Questionnaire for Medication (TSQM-9).[62-64] Items ask participants to rate their satisfaction with different aspects of their treatment regimen on a 7-point scale with endpoints labeled as “extremely satisfied” and “extremely dissatisfied”. The TSQM-9 has three subscales: Effectiveness, Convenience, and Overall Satisfaction. Internal

consistency has been demonstrated in past research with Cronbach's alpha exceeding 0.80 for each subscale.[62] The Overall Satisfaction subscale has demonstrated the greatest sensitivity to change following changes in therapy.[65]

**Satisfaction with Medication Information** will be assessed using the 17-item Satisfaction with Information about Medicines Scale (SIMS).[66] Items ask participants to rate the amount of information they have received about different aspects of their medications (e.g., what the medicine is for, how it works, whether it has side-effects). Responses range from "too much information" to "no information needed". Responses are summed to yield a total sore with higher scores reflecting greater satisfaction with amount of information received. In developmental studies, Cronbach's alpha for the total score ranged from 0.81 to 0.91 across eight different chronic illness subgroups.[66] The SIMS has also been shown to be sensitive to change following participation in a patient-centered counseling intervention.[67]

**Arthritis Self-Efficacy** will be assessed using the 8-item Arthritis Self-Efficacy Scale.[68,69] Items assess confidence in one's ability to manage arthritis pain in different situations (e.g., keep pain from interfering with things you want to do). Responses will be recorded on a 10-point scale with endpoints labeled "very uncertain" and "very certain". This measure has been widely used in arthritis patient populations and has been shown to have excellent psychometric properties, including high internal consistency (Cronbach's alpha generally exceeds 0.90) and sensitivity to change following participation in illness self-management programs.[70,71]

**Distal Secondary Outcomes:** The investigators will assess six distal outcome variables reflecting different aspects of health-related quality of life: Illness Intrusiveness, Health Distress, Depression, Fatigue, Disease Activity, and Global Health Status. Our remaining distal outcome variables were Objective Health Literacy, Subjective Health Literacy, and Medication Adherence.

**Illness Intrusiveness** will be assessed using the 13-item Illness Intrusiveness Ratings Scale. Participants will be asked to rate the degree to which their "illness and/or its treatment" interferes with activities that are essential for quality of life (e.g., work, recreation, finances, social relationships).[72] Responses will be recorded on a 7-point response scale with endpoints labeled, "not very much" and "very much." The instrument can be scored by either summing across all items to obtain a total score or computing separate scores for three subscales: relationships and personal development (family relationships, social relationships, community and civic involvement), intimacy (relationship with partner and sex life), and instrumental (work, finances). Cronbach's alpha for the total score, which The investigators used in this study, has been found to range from 0.78 to 0.97 across 36 different health conditions.[73]

**Health Distress** will be assessed by the 4-item measure developed by Lorig and colleagues.[74] This measure was adapted from the Medical Outcomes Study health distress scale for use in arthritis populations.[75] The adapted measure has demonstrated high internal consistency and responsiveness to change following completion of an arthritis self-management course.[74]

**Depression** and **Fatigue** will be assessed using the computer adaptive testing version of the Neuro-QOL (Quality of Life in Neurological Disorders) version 1.0 item bank.[76-78] These measures will be administered using the Assessment Center℠ Application Programming Interface (API) which is available through REDCap. The measures will be automatically scored by the API. Neuro-QOL measures have undergone substantial testing in previous research and have demonstrated both reliability and validity across diverse patient populations.[78]

**Disease Activity** will be assessed using the RAPID3 (Routine Assessment of Patient Index Data).[79,80] This patient-reported outcome measure has three components: physical function, pain, and global illness impact (i.e., "Considering all the ways in which illness and health conditions may affect you, please indicate how you are doing?"). Scores for each component are equally weighted and summed to calculate a total score. This measure has been shown to distinguish between active and control treatments in two clinical trials evaluating the efficacy of a biologic RA medication. In addition, the RAPID3 is one of the disease activity measures identified in the 2012 American College of Rheumatology Guidelines for the treatment of RA, which recommend using a treat-to-target strategy based on current disease activity.[10]

**Global Health Status** will be assessed by a single item asking participants to rate their current health on a 5-point scale from "1=Excellent" to "5=Poor". This item has been shown to predict mortality and health care utilization as well as multi-item health status measures.[81]

**Health Literacy**. The investigators will assess health literacy using both subjective and objective measures. The subjective measure, developed by Chew and colleagues[82,83], includes three items: "How confident are you filling out medical forms by yourself?", "How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?", and "How often do you have problems learning about your medical condition because of difficulty reading written material?" Each item will be answered on a 5-point scale ranging from 0 to 4, with higher values reflecting lower health literacy. In past research these items have demonstrated construct validity by correctly classifying individuals determined to have inadequate health literacy using either the REALM or the S-TOFHLA.[83] In the current study, the investigators will sum participant responses across the three items and reverse score the sum to yield a summary score with higher values reflecting higher health literacy.

The investigators will assess objective health literacy using the Newest Vital Sign (NVS).[84] This measure asks participants to look at the nutrition label from a pint container of ice cream. While looking at the label, participants are asked six questions (e.g., "If you ate the entire container, how many calories would you eat?"). Correct answers will be summed and then transformed to a 100 point scale, reflecting the percentage of questions answered correctly. In previous research, this measure has demonstrated internal consistency (i.e., Cronbach alpha =0.76) and construct validity (strong correlations with TOFHLA). Because the investigators will administer this measure twice in the current study, the investigators were concerned that memory effects would artificially inflate scores at the second assessment. Therefore, the investigators created a second version of the NVS based on the same ice cream container label, but with slightly modified questions. Participants will complete one version at baseline, determined randomly and balanced across participants, and the other version at the 6-month follow-up.

**Medication Adherence** will be assessed by a single question that asks: "All things considered, how much of the time do you use your RA medications EXACTLY as directed?" Responses will be recorded on a 100-point visual analog scale with endpoints labeled "None of the Time" and "All of the time".

**Other Participant Characteristics:** For descriptive purposes, The investigators will also collect the following socio-demographic information from study participants: age; gender (male, female); race (African-American, American Indian or Alaskan Native, Asian, Native Hawaiian, or Other Pacific Islander, White, Other); ethnicity (Hispanic, non-Hispanic); education (less than high school, high school diploma only, some college or technical school, college degree); marital status (never married, married, widowed, divorced, separated); and ability to afford medications (no trouble, a little trouble, a lot of trouble).

### 5.2 Pharmacokinetic Evaluation ( if applicable)

Not applicable

### 5.3 Safety Evaluations

Not applicable

## 6 STATISTICAL CONSIDERATION

### 6.1 Primary Endpoint

Informed Decision-Making

### 6.2 Secondary Endpoint

See Table 1 appended

## 6.3 Statistical Methods

**Preliminary Analyses:** Characteristics of study participants will be presented, stratified by study group, using means and percentages, depending on the measurement properties of the variables involved. Statistical comparisons will be made using linear regression models for continuous variables and chi-square tests for categorical variables. All data analyses will be performed using SAS PC, version 9.4 (SAS Institute, Cary, NC).

**Primary Analyses:** The primary outcome variable is Informed Decision-Making assessed at the 6-month follow-up. The investigators will test the following hypotheses using logistic regression methods.

1. Participants will be more likely to meet the criteria for Informed Decision-Making at the 6-month follow-up if they were assigned to receive written medication information via the DrugFactsBox® format compared to the Other CMI format.
2. Participants will be more likely to meet the criteria for Informed Decision-Making at the 6-month follow-up if they were assigned to receive gist reasoning training, delivered via the SMART Program, compared to those who were not assigned to receive this training.
3. Participants will be more likely to meet the criteria for Informed Decision-Making at the 6-month follow-up if they were assigned to receive medication information via the DrugFactsBox® format **combined with** gist reasoning training, delivered via the SMART Program, compared to individuals in the other three groups.

The regression model will control for Informed Decision-Making at baseline (0=Did not meet criteria for Informed Decision-Making, 1=Met criteria for Informed Decision-Making) and indicator variables for each intervention indexing whether the participant was assigned to SMART Training (0=No, 1=Yes) and the DrugFactsBox® group (0=No, 1=Yes). In separate regression models, the investigators will also test three 2-way interactions. The first interaction will assess whether the effects of the two interventions are dependent of one another (Hypothesis 3). The other interaction terms will assess whether the effects of each intervention varies as a function of whether participants met the criteria for Informed Decision-Making at baseline. Statistical significance will be evaluated with alpha (2-tailed) set at 0.05. When significant interaction terms are observed, the investigators will use stratified analyses to examine the nature of the interaction.

In the main analysis, the investigators will use an *intention-to-treat* strategy, with individuals included in the analysis based on random group assignment, without regard to whether they were actually exposed to the intervention. However, the investigators will only include participants with nonmissing data at the 6-month follow-up. In addition to the main analyses, the investigators will perform three sets of sensitivity analyses to

assess the robustness of the findings. The first set of sensitivity analyses will use an *as-treated* approach and include only people with nonmissing data at the 6-month follow-up. Individuals will be included in this analysis only if they actively participated in the interventions. For the DrugFactsBox®/Other CMI groups, the investigators defined active participation as viewing at least one page on the DrugFactsBox®/Other CMI website. For the SMART group, the investigators will define active participation as attending at least 3 of the 4 training sessions. Note that all individuals in the No SMART group will be included in the *as-treated* analyses because they will not have an opportunity to participate in any training. In the second set of sensitivity analyses, the investigators will use an *intention-to-treat* approach and impute missing data using the last-observation-carried forward method for individuals who do not complete the 6-month follow-up. In the final set of sensitivity analyses, the investigators will use as *as-treated* approach and impute missing data using the last-observation-carried forward method.

**Secondary Analyses:** The investigators will use the same analytic strategy to examine the effect of the intervention on 18 secondary outcomes assessed at the 6-month follow-up: Medication Self-Management Knowledge, Selective Learning, Complex Abstraction, Lesson Quality, Use of the RA Self-Management Website, Participation in the BetterChoices,BetterHealth program, Self-Efficacy, Overall Medication Satisfaction, Global Treatment Satisfaction, Medication Adherence, Objective Health Literacy, Subjective Health Literacy, Disease Activity, Illness Intrusion, Illness Distress, Global Health, Depression, and Fatigue. In these analyses, the investigators will use either logistic or linear regression, depending on the measurement properties of the outcome variable. Due to the number of endpoints examined in these secondary analyses, the investigators will use the Hochberg method to adjust for the potential inflation of Type I error.[85]

**Exploratory Analyses:** The investigators will use the same analytic strategy to evaluate intervention effects at the 6-week and 3-month follow-ups. However, these analyses will be considered exploratory and are designed to capture any transient intervention effects that may occur.

## 6.4 Sample Size and Power

The primary outcome variable will be Informed Decision-Making, assessed at the 6-month follow-up. Our targeted sample size will be 300 (75 in each of the four study arms). Power analyses performed a priori indicated that a sample of this sample size would provide 80% power to detect a between-group difference of 25% in the percentage of participants classified as meeting the criteria for informed decision-making (e.g., 60% versus 35% among individuals assigned to the DrugFactsBox® versus Other CMI groups, respectively). This anticipated effect size was based on that observed in previous studies[55] and corresponds to a slightly smaller than moderate sized effect using the criteria developed by Cohen.[86] These power calculations were performed with

alpha (2-tailed) set at 0.05 and allowed for 15% attrition from baseline to final follow-up.

### 6.5 Interim Analysis

Not applicable

## 7 STUDY INTERVENTION (drug, device or other intervention details)

The investigators will evaluate the effectiveness of two separate interventions: the DrugFactsBox® format (compared to Other CMI, primarily Medication Guides) and gist reasoning training delivered via the SMART Program (compared to standard care). Each intervention is described below.

**DrugFactsBox® Format.** The original DrugFactsBox® format consisted of a standardized 2-page summary that followed plain language guidelines and best practices to enhance comprehension among individuals with limited literacy or numeracy skills.[87,88] Research involving nationally representative samples has demonstrated that the DrugFactsBox® format improves (1) patient comprehension of medication risks and benefits and (2) patient judgment and decision-making.[88-90] To produce Drug Facts Boxes, information from FDA drug approval documents and systematic reviews published in the scientific literature are examined to extract information concerning drug benefits and harms, as well as areas of scientific uncertainty that are not always conveyed clearly to the general public. The information extracted is used by medical experts to create a Drug Facts Box. Each section in a Drug Facts Box is clearly labeled and provides quantitative information concerning the drug's potential benefits and harms in comparison to treatment alternatives or no treatment (if data are from a placebo-controlled trial). This type of quantitative information concerning potential benefits and harms is missing from FDA-approved medication guides and other types of CMI commonly given to patients in the United States when prescriptions are dispensed.

For this study, the investigators will create a website that contains 16 Drug Facts Boxes for those medications most commonly used to treat RA in the United States (i.e., abatacept, adalimumab, certolizumab, etanercept, golimumab, hydroxychloroquine, infliximab, leflunomide, methotrexate pill, methotrexate shot, prednisone, rituximab, sulfasalazine, tocilizumab infusion, tocilizumab shot, and tofacitinib). A pill bottle icon for each of these medications will appear on the website landing page. When the icon for a medication is clicked, an overview of the medication will appear. The overview will include a section labeled *Bottom Line* which contains a narrative summary of potential medication benefits and harms, emphasizing bottom-line gist. The overview page will also provide links to other pages within the website that contain additional information about the medication. These links will be labeled: Trials, Side Effects, How to Use, Lifestyle Changes, and Interactions. The Trials page will provide quantitative information

concerning potential medication benefits and harms, mirroring the original DrugFactsBox® format.

Effects of the DrugFactsBox® format will be evaluated in comparison to other types of written CMI. All participants assigned to receive Other CMI will be given access to a website that contains CMI for the same 16 medications listed above. For medications that have an FDA-approved Medication Guide (i.e., abatacept, adalimumab, certolizumab, etanercept, golimumab, infliximab, rituximab, tocilizumab infusion, tocilizumab shot, and tofacitinib), the website will provide a link to the Medication Guide. For the remaining medications (i.e., hydroxychloroquine, leflunomide, methotrexate pill, methotrexate shot, prednisone, and sulfasalazine), the website will provide a link to CMI developed by the American Society of Health-System Pharmacists®. These materials are similar to the CMI that is given to patients in the United States when prescriptions are dispensed. The DrugFactsBox® website and the Other CMI website will both allow participants to print a hard copy of the materials, if desired.

Because federal law mandates that Medication Guides be given to patients when certain medications are dispensed, the investigators view them as a component of usual care. Nonetheless, the investigators are aware of no research demonstrating that the Guides improve patient-centered health outcomes. Moreover, research suggests that many patients have difficulty understanding and using the information contained in the Guides.[31-35,91] Comprehension of information contained in the Guides is particularly low among older patients and those with limited health literacy.[32,33]

**SMART Program.** The SMART Program was designed to enhance gist reasoning ability by training participants on the use of three metacognitive strategies: Strategic Attention (e.g., ignoring or eliminating distractions to facilitate single-minded focus on understanding the specific topic at hand, prioritizing health issues/problems with greatest impact on daily function, understanding signs and symptoms of brain fatigue and taking mental breaks to recharge), Integrated Reasoning (e.g., strengthening integrative mental capacity to synthesize general as well as medical information from multiple sources), and Innovation (e.g., examining multiple perspectives and information sources to best understand the information at hand, comparing and contrasting information to help determine the best decision, asking insightful questions that involve considering information from differing perspectives).[92] In randomized controlled trials, the SMART Program has been shown to strengthen gist reasoning ability especially as evidenced in efficient synthesis and comprehension of complex information encountered in everyday life such as news articles and medical information.[60,92-94] Evidence has also demonstrated generalized benefits of improved performance on cognitive, neural and functional measures immediately post training and 3-6 months post-training.[92] Thus, considerable evidence supports the effectiveness of the SMART program in enhancing gist reasoning ability. However, this will be the first

study to examine whether the program enhances patient ability to understand written prescription drug information and whether better understanding translates into improved decision-making and health outcomes.

Effects of the SMART Program will be evaluated in comparison to standard care. Because participants will be recruited from multiple, geographically diverse sites, the investigators will not attempt to measure the content of care received. However, because the type of gist reasoning training provided by the SMART Program is very innovative, the investigators believe that it is unlikely that any participants in the comparison group had access to similar programs.

# 8 STUDY INTERVENTION ADMINISTRATION(if applicable)

Participants will be randomized to study arm on a 1:1:1:1 basis. Prior to the start of participant recruitment, the principal investigator will generate a random allocation sequence using PC-SAS® (version 9.4). Random numbers will be generated in blocks of 20 to ensure balance across the four study groups over the entire course of data collection. The random number sequence will be imported into the REDCap tracking database used by the project director, working out of the UNC-Chapel Hill office, to record the name and contact information for study participants as they are enrolled in the study. To ensure allocation concealment, the REDCap database will be programed so that the group assignment variable: (1) cannot be viewed until after the patient contact information has been entered and (2) cannot be changed after the patient contact information has been entered. All personnel involved in data collection and delivery of the SMART program were blinded to participant group assignment. Because the study involves minimal risk, the investigators have no plans to unblind participants or study personnel. However, participants will be encouraged to report any problems they experience to the research staff so that unanticipated problems might be identified.

Immediately following completion of baseline data collection, participants will be emailed a link to either the DrugFactsBox® website or the Other CMI website, depending on the group to which they will be randomized. To track website utilization, participants will be assigned a unique username that they will be required to enter each time they visited the website. Participants will be free to access the site whenever they chose and will have access to the site from the time their username is assigned until the end of the study. At the conclusion of the study, tracking data will be downloaded and used to assess how often each participant visited the website and the specific pages viewed.

Participants randomized to the SMART Program will be contacted by staff at the Center for BrainHealth at the University of Texas at Dallas following completion of baseline data collection, by email and telephone, to enroll them in the next SMART Program. The

program will be delivered by Center research personnel certified to provide the program using an online video conferencing platform that permits synchronous, audio and visual communication between trainers and participants. Participants will only need a computer or mobile phone with internet access to participate. Initially, the program will be delivered via four 60 to 90 minute sessions, spanning a one month period. In most cases, the program will be delivered in small groups with three to four participants. However, the program will be delivered one-on-one, if needed to accommodate participant schedules.

# 9 SAFETY MANAGEMENT

This project is associated with minimal risk. Therefore, the investigators have not incorporated a formal Data and Safety Monitoring Board. The project will be monitored by Drs. Blalock, Karp, Solow, and Carpenter. Dr. Blalock will meet with the Project Director on a weekly basis to monitor any adverse effects reported by study participants. Drs. Blalock, Karp, Solow, and Carpenter will meet quarterly to monitor safety concerns. Study participants will be instructed to call the Project Director if they experience any problems that they attribute to study participation. To make it easy for participants to contact the Project Director if needed, the investigators will give all participants a magnetized card with the Project Director's name and telephone number to place on their refrigerator. The Project Director will record each problem reported in a database created for that purpose. Dr. Blalock and the Project Director will discuss all problems reported on a weekly basis. Each event reported will be classified into one of the following categories:

1. Mild Adverse Event – Event results in mild or transient discomfort, not requiring intervention or treatment; does not limit or interfere with daily activities.
2. Moderate Adverse Event – Event is sufficiently discomforting so as to limit or interfere with daily activities; may require interventional treatment.
3. Severe and Undesirable Adverse Event – Event results in significant symptoms that prevents normal daily

The interventions the investigators will test involve minimal risk. Therefore, the investigators have no plans to withdraw individual participants for any reason. However, if a participant becomes upset concerning any study procedures, the investigators will ensure that they understand that they have the right to withdraw from the study at any time, without penalty.

# 10 DATA COLLECTION AND MANAGMENT

Data will be collected primarily via telephone interviews, and self-administered, Internet-based surveys using REDCap and Qualtrics. All individuals involved in the study will be trained as to the confidential nature of all data collected. In addition, all personnel will complete ethics training in accordance with IRB policy before they are

allowed to have any contact with study participants or data obtained from study participants. All participants will be assigned a unique identifying number that will allow the investigators to track them over the course of the study. A key linking participants' names and contact information to this unique identifier will be stored in an encrypted file stored on a password protected computer housed behind a firewall on the UNC-CH computer system. Only the principal investigator and project director will have access to this encrypted file. Participants will not be identified in any report or publication about this study. All sharing of research documents between research team members will occur via a secure online drive. All information stored in computer files will be password-protected and passwords will be changed on a regular basis. Information sent by clinical coordinators to the central project office as part of the recruitment process will be sent to a fax machine located in a private office, dedicated to this research project. The office will be locked when study personnel are not present. All information collected that contains the names of study participants will be kept in locked filing cabinets when not in use..

The names of patients identified at participating clinics and the date of their next visit will be entered into an on-line database using the UNC REDCap Software. Data entered using the REDCap system are maintained on secure, HIPAA-compliant servers. Each clinic site will have access only to information entered at their site. If a hard copy of information in this database is needed to facilitate recruitment, staff working on the project will be instructed to shred the hard copy at the end of each clinic day.

## 11 RECRUITMENT STRATEGY

Please see Section 3.3 "Study Duration, Enrollment and Number of Subjects"

## 12 CONSENT PROCESS

We will obtain written informed consent from participants. We will go over the consent form with potential participants, solicit questions they may have about the study, obtain the participant's signature on the consent form, and provide the participant with a copy of the consent form. Consent will be obtained by clinical coordinators working at clinic sites and research assistants and the project director working in the central project office at the University of North Carolina at Chapel Hill. We will emphasize to all potential participants that they are not obligated to take part in the study and that they may decline study participation for any reason, and without providing a reason, without any negative consequences. The investigators do not plan to enroll individuals who are decisionally-impaired or lack sufficient English-language proficiency to understand study procedures and the potential risks and benefits associated with participation.

## 13 PLANS FOR PUBLICATION

The investigators plan to publish up to three papers reporting study findings in the peer-reviewed literature.

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# 15 APPENDIX

## Figure 1. Conceptual Framework

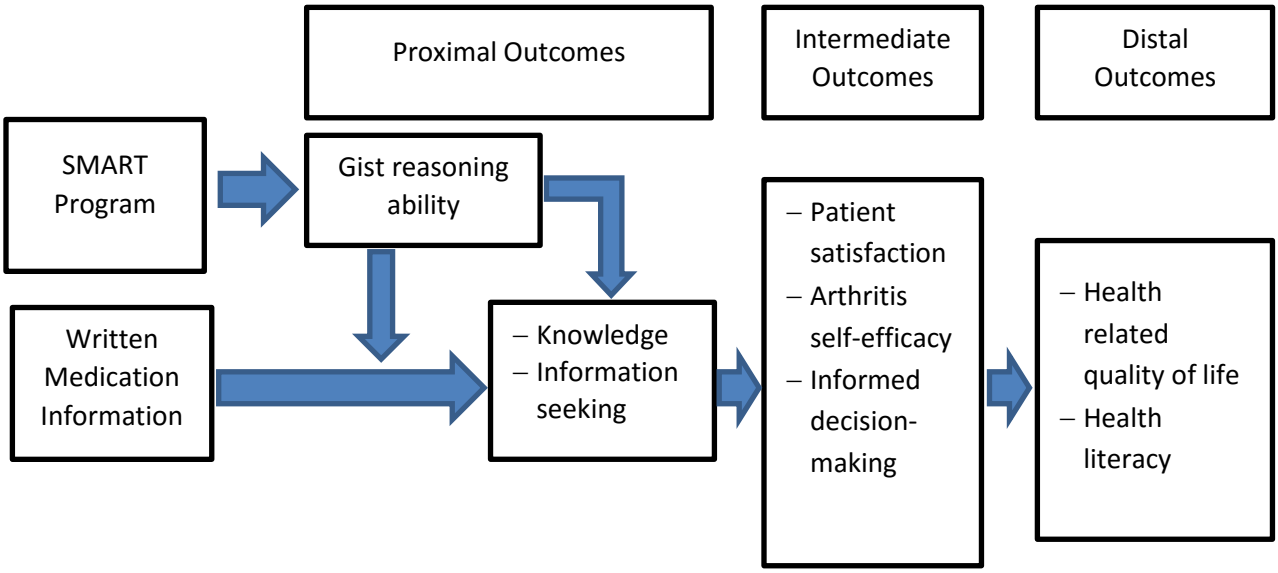

**Table 1. Summary of study measures**

| Variable | Time Assessed | Data Collection Instrument | Range | Baseline Alpha |
|---|---|---|---|---|
| Knowledge | B, 6W, 3M, 6M | Telephone Interview | 0 to 100 | 0.84 |
| Values | B, 6W, 3M, 6M | Self-Administered Questionnaire | -15 to +15 | 0.67 |
| DMARD Usage | B, 6W, 3M, 6M | Self-Administered Questionnaire | 0=Not using any DMARDS 1=Using 1+ DMARDS | NA |
| Informed Decision-Making | B, 6W, 3M, 6M | Composite measure based on Knowledge, Values and DMARD Usage | 0=Did not meet criteria 1=Met criteria | NA |
| Gist Reasoning Ability: | | | | |
| Complex Abstraction | B, 6W, 3M, 6M | Self-Administered Questionnaire† | 0 to 8 | NA |
| Lesson Quality | B, 6W, 3M, 6M | Self-Administered Questionnaire† | 0 to 5 | NA |
| Selective Learning | B, 6W, 3M, 6M | Telephone Interview | 0 to 264 | 0.67 |
| Verbatim Recall | 6W | Telephone Interview | 0 to 2 | 0.14†† |
| Medication Self-Management Knowledge | 6M | Telephone Interview | 0 to 100 | 0.36 |

| Variable | Time Assessed | Data Collection Instrument | Range | Baseline Alpha |
|---|---|---|---|---|
| Information Seeking: | | | | |
| Use of RA Self-Management Website | 6M | NA | 0=Never accessed website 1=Accessed website 1+ times | NA |
| Participation in BetterChoices, Better Health | 6M | NA | 0=Did not participate in all 6 sessions 1=Participated in all 6 sessions | NA |
| Treatment Satisfaction: | | | | |
| Global | B, 6W, 6M | Self-Administered Questionnaire | 0 to 100 | 0.83 |
| Effectiveness | B, 6W, 6M | Self-Administered Questionnaire | 0 to 100 | 0.90 |
| Side-Effects | B, 6W, 6M | Self-Administered Questionnaire | 0 to 100 | 0.82 |
| Convenience | B, 6W, 6M | Self-Administered Questionnaire | 0 to 100 | 0.86 |

| Variable | Time Assessed | Data Collection Instrument | Range | Baseline Alpha |
|---|---|---|---|---|
| Satisfaction with Medication Information: | | | | |
| Overall | B, 6W, 6M | Self-Administered Questionnaire | 0 to 17 | 0.88 |
| Actions | B, 6W, 6M | Self-Administered Questionnaire | 0 to 9 | 0.78 |
| Problems | B, 6W, 6M | Self-Administered Questionnaire | 0 to 8 | 0.85 |
| Arthritis Self-Efficacy | B, 6W, 6M | Self-Administered Questionnaire | 0 to 100 | 0.87 |
| Illness Intrusiveness: | | | | |
| Overall | B, 6M | Self-Administered Questionnaire | 0 to 100 | 0.90 |
| Relationships | B, 6M | Self-Administered Questionnaire | 0 to 100 | 0.85 |
| Instrumental | B, 6M | Self-Administered Questionnaire | 0 to 100 | 0.71 |
| Intimacy | B, 6M | Self-Administered Questionnaire | 0 to 100 | 0.82 |
| Health Distress | B, 6M | Self-Administered Questionnaire | 0 to 5 | 0.91 |

| Variable | Time Assessed | Data Collection Instrument | Range | Baseline Alpha |
|---|---|---|---|---|
| Depression | B, 6M | Self-Administered Questionnaire | T-Score: Mean =50, SD=10 in reference population | NA |
| Fatigue | B, 6M | Self-Administered Questionnaire | T-Score: Mean =50, SD=10 in reference population | NA |
| Disease Activity | B, 6W, 3M, 6M | Self-Administered Questionnaire | 0 to 10 | 0.81 |
| Global Health Status | B, 6M | Self-Administered Questionnaire | 1 to 4 | NA |
| Subjective Health Literacy | B, 6M | Self-Administered Questionnaire | 0 to 4 | 0.80 |
| Objective Health Literacy | B, 6M | Telephone Interview | 0 to 100 | Version A: 0.60 Version B: 0.49 |
| Medication Adherence | B, 6M | Self-Administered Questionnaire | 0 to 100 | NA |

†A separate online, self-administered questionnaire was used to assess Gist Reasoning Ability. It was completed before participants did the questionnaire assessing other study measures.

††This variable was only assessed at the 6-week follow-up. Therefore, the alpha reported is for that time point.

NOTE: For all variables except Global Health Status, higher values reflect higher levels of the attribute measured. For Global Health Status, higher values reflect poorer health status.