A. Title: Web (YouTube) based educational intervention to improve patient-physician awareness of cardiovascular risk in rheumatoid arthritis

B. Organizational detail: Rush is a not-for-profit health care, education and research enterprise. Rush University Medical Center (RUMC) encompasses a 664-bed hospital. The mission of RUMC is to provide the best care for our patients. A unique combination of research and patient care has earned Rush national rankings in 9/ 16 specialty areas in *U.S. News & World Report*'s 2013-14 America's Best Hospitals issue. Our education and research endeavors, community service programs are dedicated to enhancing excellence in patient care in the Chicago area. RUMC's core values — innovation, collaboration, accountability, respect and excellence —translate into highest quality patient care. The Department of Medicine's leadership is dedicated to supporting research endeavors to improve patient care. Hence, *both the organization and departmental leadership are committed to improving patient care and research.*

The Division of Rheumatology at RUMC (and its affiliated institutions) provides care to patients with rheumatoid arthritis (RA), and thus has access to large numbers of RA patients to pursue research. The division includes 15 salaried MD rheumatologists at two clinical locations. At RUMC, we see approximately 500 RA patients per year. John Stroger Hospital (JSH) is affiliated and in vicinity of RUMC. The primary investigator (PI) has clinical privileges at both the hospitals. The JSH's Rheumatology division provides longitudinal care for rheumatology patients, mostly with poor or no medical insurance. Approximately 1000 RA patients per year are seen by Rheumatology at JSH. *Our combined (RUMC and JSH) Rheumatology division's leadership and faculty are actively engaged in investigator-initiated clinical trials, including quality improvement projects.*

The Department of Preventive Medicine at RUMC has been specializing in design and testing of rigorous multi-level interventions for cardiovascular risk reduction. The proposed study will have access to its statistical and methodological expertise, including experts in cardiovascular prevention, cardio-metabolic conditions and behavioral science. *The resources of the Department of Preventive Medicine will enhance the methodological rigor* and likelihood of success of this study.

Other resources available to the PI: *On site Center for Clinical Studies*, a busy clinical trials unit located within the Division of Rheumatology, helps with study coordination and patient recruitment; and clinical assessments are performed on site. It has been conducting clinical research and clinical trials successfully for more than 15 years. Approximately 30-40 protocols/year are performed, which include investigator-initiated research and multi site clinical trials in RA and other conditions. It maintains a disease-oriented database of potential study volunteers. Other Center resources include *nurse coordinators, a regulatory affairs specialist, patient recruiters, phlebotomists, administrative, clerical and front-office staff*, and physician faculty of the Division of Rheumatology. Two *conference rooms with audio-visual equipment* are available. In addition, *networked computer facilities* are available for study coordination, statistical and data analysis, and database management.

Interdisciplinary Leadership of the proposed project and their specific roles are as follows:

Meenakshi Jolly, MD, MS is the lead PI and an Associate Professor in Department of Medicine (Division of Rheumatology). She is responsible for the concept, study design, regulatory aspects, patient recruitment, data procurement, data management, analysis, interpretation, educational intervention (EI), manuscript preparation and presentations. The PI is an experienced and trained clinical investigator in patient reported outcomes and efforts to optimize health outcomes. She has a record of accomplishment with successful completion of projects; has published in peer-reviewed journals and presented her research nationally and internationally.

Rasa Kazlauskaite, MD is an Assistant Professor of Preventive Medicine & Internal Medicine (Preventive Cardiology & Endocrinology, Diabetes and Metabolism). Her expertise is in cardiovascular risk screening and management, and is a PI on NIH funded studies. Her role will be in study design, development of study surveys (CVR awareness) and intervention modules (expert opinion), data interpretation and manuscript preparation.

Lisa Walt, PhD is Experimental Health and Social Psychologist at the Department of Preventive Medicine. She has considerable experience in the social cognitive, interpersonal communication, and persuasion arenas as related to risk behaviors and prevention. Her role will be in development of study surveys (methodological) and intervention modules (persuasion and social cognitive expertise), data interpretation and manuscript preparation.

Augustine Manadan, MD is an Associate Professor and Division Head of Rheumatology at JSH. He will assist with patient recruitment, data accrual, interpretation and manuscript preparation.

Joel A Block, MD, is Professor and Division Head of Rheumatology at RUMC. He will assist with study design, regulatory aspects, surveys modifications and development of case scenarios for PHCP surveys, patient recruitment, data accrual, interpretation and manuscript preparation.

C. Goal: Our goal is to develop and pilot-test a multi-level web-based EI aimed to improve cardiovascular risk awareness (CVRA) in rheumatoid arthritis (RA).

D. Objectives: We propose to conduct this study in two phases with the following aims:

1. EI development phase.

Aim 1. To develop a multi-level web-based EI for improving CVRA targeted to the patients with RA and their primary health care providers (PHCPs; see definition in section F). The intervention will be designed over the first 6 months in collaborative effort of ***patients*** and the ***trans-disciplinary panel of experts*** in rheumatology, preventive cardiology/endocrinology, and experimental health and social psychology.

2. Pilot-testing phase.

Aim 2A. To compare changes in CVRA in RA patients (a) after web-based EI. We hypothesize a 20% increase in CVRA (measured using standardized survey) at 2-3 months post intervention; (b) among patients with and without web-based EI. We hypothesize significantly greater improvement in CVRA (using standardized survey) among RA patients with EI as compared to RA patients without EI, at 2-3 months.

Aim 2B. To explore changes in cardiovascular risk screening (CVRS) at the primary health care visits among RA patients with and without EI, at one year.

E. Assessment of Need: Health care and disease burden of cardiovascular disease among men and women is substantial. Cardiovascular disease (CVD) is the leading cause of death and a major cause of disability worldwide. Coronary artery disease (CAD) is the leading cause of death worldwide. In the United States, CVD accounted for 34.4 % of the 2.4 million deaths in 2003, and remains a major cause of health disparities and rising health care costs. In 2006, health care spending and lost productivity from CVD exceeded $400 billion. Traditional risk factors for CVD are male gender, dyslipidemia, hypertension, diabetes, smoking and family history of CVD. Women have unique risk factors for CAD (2), and CAD's impact on women traditionally has been under appreciated due to higher rates at younger ages in men. The death rates from CAD in US women 35-54 yrs of age are increasing. Heart disease is the leading cause of death in women in every major developed country and most emerging economies. First women-specific recommendations for CVD prevention were published in 1999. In 2007, CVD still caused approximately 1 death/minute among women in the US. Major gaps among patients and physicians remain regarding CVRA in women.

The American Heart Association now recognizes systemic autoimmune diseases (e.g. RA) as an independent CVD risk in women (1). RA, the most common autoimmune arthritis, affects at least 1.3 million US adults. 1-3% of women may get RA in their lifetime. Usually, 75% of RA patients are women, and between 40-50 yrs. Major cause of mortality in RA is CVD. As compared to general population, CVD morbidity in RA is 1.5-2.0 folds (3). The mortality gap between RA and the general population has widened (2). Ischemic heart disease in RA is often silent, and precedes myocardial infarction in RA. Identification and addressal of modifiable traditional CVR factors in patients with RA is important, besides simultaneously targeting RA-specific risks. The increased CVD risk in RA cannot be explained by traditional risk factors. Immune dysregulation, systemic inflammation, plaque instability, impaired coronary reserve, elevated thrombotic markers, medications (corticosteroids and non-steroidal anti-inflammatory medications) and extra-articular manifestations contribute to increased CVD risk in RA (2-4). The absolute risk of CVD is highest for elderly, male patients with RA, whereas relative risk is highest among young female patients with RA (5). Innala et al reported traditional CVD risks to explain new CVD events in very early RA, and it being potentiated by high disease activity (6). Hence, *attention to both traditional and RA-specific factors* to decrease CVD morbidity and mortality in RA is required.

Primary preventive screening before the onset of CVD is key to identifying modifiable traditional CVD risk factors (7). European League against rheumatism (EULAR) guidelines recommends CVRS using national guidelines for all RA patients (5). It has been suggested that in patients with low CVD risk and inactive RA, a lower frequency of assessment (e.g. every 2-3 years), could be adopted. Currently there are no guidelines on this from the American College of Rheumatology. National Cholesterol Education Program guidelines recommend checking for dyslipidemia in adults ≥ 20 yrs every 5 years for the general population; to have this tested more often if either there is dyslipidemia on screening, male gender >45 yrs, or a woman > 50 years, HDL <40 mg/dl, or if there are other risk factors for CVD. Current US preventive services

task force guidelines strongly recommends dyslipidemia screening for men aged ≥ 35 yrs, and for men between 20-35 yrs only if they are at increased risk of CVD. For women, dyslipidemia screening is only recommended if they are at risk for CVD by them. Using these guidelines, RA patients of any gender and age would be eligible for CVD and dyslipidemia screening.

Patient-Physician based EIs to target CVD risks are successful and can improve health outcomes. Several studies show that EI targeting CVD risks can improve outcomes and health behaviors. In a study aimed at improving CVRA, a tailored EI and CV risk screening were offered in two communities. Greater knowledge was noted on post screening; 44% had consulted their internist, while 69% made at least one healthy behavior change (8). Diabetes EI is associated with self-management behavior (9-10), thus improving care outcomes, without having a major impact on health care costs (10).In another study aimed at improving diabetes care, an EI that targeted both the patient and physician, demonstrated the largest and most consistent drop in hemoglobin A1C, as well as the lowest treatment cost (11), suggesting that the patient-physician dyad based EI, may be a better target than either person alone, as is being proposed in this project.

Web-based EI (including video) have been found to be effective in improving practice patterns and health outcomes in several studies (12-17). Web-based EI have several advantages over conventional class room based EI as they provide flexibility, privacy and time efficient utility to users. For health services providers web-based EI can provide easy and quick access, globally to vast number of patients, efficiently and effectively, quick implementation, with least administrative and financial burden.

Current Clinical Gaps Identified: Status of CVRS, lipid screening or treatment of dyslipidemia in RA is far from optimal, even in Medicare age group patients. Traditional CVD risks and RA-specific risk/s are well noted be to be associated with greater CVD in RA. However, the presence of RA does not always trigger CVRS or treatment. In RA patients (≥ 65 years), primary lipid screening was performed in 45% (7), an age group where all patients should receive dyslipidemia screening, regardless of their RA status. Adjusted predicted probabilities of lipid screening were 26% for RA patients seeing rheumatologist alone, to 44-48% for patients with some primary care physician visits (7). In another study, one third of RA patients did not have any lipid testing (18- 19). Furthermore, upto 26% of RA patients without CVD have sufficiently high risk for CVD to require statin therapy, yet and most of them remain untreated (20).

Potential reasons for poor CVRS in RA, despite the indication may include lack/limited knowledge among RA patients and their PHCP's about the CVD risk. Lack of knowledge in general about CVD risks in women and their PHCPs has been previously reported. Women do not always perceive themselves to be at risk for CVD (21). Furthermore, existent medical literature is lacking in published studies in the United States in RA that (i) ascertain patient or physician awareness of CVD risks, or (ii) compare the rates of CVRS pre and post EI against RA patients receiving usual care from PHCP. These are lost opportunities to make PHCP's aware of the existent gap in knowledge and thus the need for changing behaviors. In a study done in United Kingdom, only 32% of general practitioners identified RA as a risk for CVD (22). They reported lack of educational resources on this matter.

Secondly, lack of clarity on primary responsibility for CVRS in RA, in a patient seeing two or more physicians, may contribute to low CVRS and treatment. RA patients who saw their primary care physician in the past year, in addition to their rheumatologist, were more likely to get CVRS by their PHCP (23). Time constraints during each visit may also burden the PHCP. Performance of CVRS to Physician Quality Reporting Initiative (PQRI) in RA may be helpful.

Currently, there are no published, effective, EI targeting patient-PHCP CVRA in RA. Furthermore, there are barriers to use of currently available EI resources (classroom style educational events) to improve CVRA among RA patients and their PCHP. These include access, need for dedicated substantial time and/or financial commitment to attend continuous medical education or other educational events, lack of flexibility, which may impose on patient care or personal time. Similar access, lack of flexibility, lack of awareness of resources available, complexity in the content delivery, need for dedicated time and financial time commitments may be encountered by RA patients. A brief, focused, simple web-based EI, if found to be effective, can overcome the above mentioned obstacles, and be made available globally , rapidly, and in a cost effective use of available resources.

F. Target Learner Audience: Primary audiences are RA patients and their PHCPs. Direct benefits from the project to RA patients are targeted in the form of improved awareness of primary and secondary prevention of CVD in RA. *PHCP refers to any health care provider identified by the RA patient as their primary health care provider*. This may be their rheumatologist, family practitioner, internist, other specialists or mid-level health providers.

G. Project Design and Methods: *G.1. Study design, number of participants, sites and duration*: As mentioned previously, the study will consist of two phases:

(i) **EI development phase** consisting of EI development by interdisciplinary, collaborative team (including RA patients), and qualitative assessments used to refine the intervention, (ii) **Pilot-testing phase.**

We propose a longitudinal of 300 RA (150 with and 150 without EI), to test for (*primary outcome*) change in CVRA at 2-3 months following web-based EI, and compare that with CVRA changes among RA patients without IE. The proposed secondary outcomes will explore the rates of CVRS via medical chart review among RA patients with and without IE. Consenting participants (RA patients (n=300) and PCHPs) will have (a) baseline survey on CVRA, followed by a short EI delivered via YouTube video (n=150), followed by immediate and 2-3-month follow up surveys, to quantitate changes in CVRA, (b) a medical record review of participating RA patients (n=300) will be undertaken (records from preceding one year duration) and at 12 months (after baseline visit) to determine the changes in CVRS in RA (Figure 1). *Only PHCPs providing care to the EI arm RA patients will receive the CVRA evaluations and the EI. Care will be taken to avoid enrollment of PCHPs providing care to RA patients not in the EI arm, to not confound the results.*

Educational approach is discussed in the section I. We expect to reach out to 600 RA patients at RUMC and JSH, with the goal of recruiting 300 RA patients over 12 months. This screening-to-enrolment ratio is consistent with previously observed 10:9 ratio for survey-based one-visit

studies at RUPC and JSH. We expect to reach our expected goal of 300 RA patients even if screening-to-enrollment ratio erodes to 10:5. *Sample size calculation*: To show an improvement of 20% in overall CVRA, with 90% power and 0.05% alpha error, we need 127 RA patients in each group.

H. Innovation: We did not find on our review of current medical literature (PubMed and Ovid Medline) using the search terms "Rheumatoid arthritis" and "educational intervention" and "web" for any existent EI studies that study patient-PHCP CVRA or utilize a YouTube based EI to improve CVRA. Furthermore, use of patient-PHCP dyad for CVR EI has not been reported. We feel confident that our study idea is original and has significant advantages over existent methods as it is easier, quicker and has significant potential applications. The you tube video EI if successful can be offered through National organizations e.g. American College of Rheumatology or Arthritis Foundation; and can be made available to large numbers of RA patients worldwide with less resources utilization and advantages of privacy, flexibility and access to users.

This project builds upon ongoing work in quality in RA in the Divisions of Rheumatology, and CVR management through Department of Preventive Cardiology. Rush has a history of cardiovascular prevention research studies through the Preventive Medicine Department. Dr. Kazlauskaite is a co-investigator in the Study of Women's Health Across the Nation and NIH – funded project on development of intervention for primary prevention of cardiovascular disease in mid-life women. She is also the PI on NIH-funded pilot study of a Lifestyle Intervention on the Metabolic Syndrome through changes in dietary intake, stress management and physical activity, working in close collaboration with Dr. Walt, who has extensive theoretical and practical expertise in health behavior modification from her work in NIH and industry-funded grants. The PI has experience in offering educational talks through you tube videos and social media for autoimmune diseases for patients and support groups, and is building on this experience to develop an active intervention in collaboration with an expert in preventive cardiology. The PI is actively involved in several projects aimed at quality improvement projects, and others relating to improving health outcomes in lupus. Dr. Jain and Dr. Manadan are involved in quality improvement projects, specifically pertaining to RA patients.

I. Outcomes Evaluation:I.1 CVRA refers to cardiovascular risk awareness, whereas CVRS refers to cardiovascular risk screening.

1. EI development phase: The primary outcome of the EI development phase will be patient-centered EI video and PHCP-centered EI video aimed at increasing CVRA in RA patients and their PHCPs. **2. Pilot-testing phase**: Primary outcomes of interest are (a) changes in CVRA after an EI among RA patients, and (b) changes in CVRA rates among RA patients with and without IE at 2-3 months. Our secondary outcome of interest is the change in rate of CVRS among RA patients with and without IE at one year. Other exploratory outcomes may include correlation between PHCPs CVRA and baseline CVRS; patient and PHCPs predictors of change in CVRS. Outcomes evaluations in terms of metrics used for the needs assessment, and addressal of gaps for each target group, and amount of changes expected are shown in Table 1 below**.**

Table 1: Outcomes evaluations, expected change and addressal of gaps.			
Aim	**Outcomes Evaluation**	**Expectation**	**Gap addressed**
Phase 1/Aim1: Development and implementation of a 30-minute web based (You Tube) educational intervention to improve patient-physician awareness for CVR in RA.	Pre testing and Credibility surveys to evaluate the feedback provided by the patients-PHCP on the need for the study, and on the ease, content and understandability, relevance of the educational module.	We expect the intervention module to be feasible and credible (user friendly, content, understandibility and relevant) in improving knowledge of CVR in RA	No educational interventions targeting patient-PHCP CVR awareness are yet available for RA patients.
Aim 2A: To compare changes in CVRA in RA patients (a) after web-based EI (b) with and without web-based EI	(a) Overall CVRA	We expect a 20% increase in CVRA at 2-3 months post EI	Patients have poor knowledge in general about overall CVR, in women and in RA. No studies exist yet in the United States in RA ascertaining patient and PHCP awareness of CVR, despite the documented increased risk of CVD in RA.
	(b) Overall CVRA	Change in overall CVRA will be significantly greater among RA with EI than non EI	There is a lack of knowledge among PHCP about CVD risks among women and RA. No studies exist yet in the United States in RA ascertaining patient-PHCP awareness of CVR, despite the documented increased CVR in RA.
Aim 2B: To explore changes in cardiovascular risk screening (CVRS) at the primary health care visits among RA patients with and without EI.	Prevalence rates of relevant CVR assessment performed by PHCP among RA patients (with and without EI)	Prevalence rates of CVRS at 1 year follow up will be significantly higher among RA patients post EI as compared to baseline. Change in prevalence rates of CVRS at 1 yr follow up will be	RA patients PHCP may not be clear on whose responsibility is it for CVR assessment, when RA patient sees ≥ 2 physicians. Status of CVRS, lipid screening or treatment of dyslipidemia in RA is far from optimal, even in Medicare age group patients. There is a lack of knowledge in general about CVD risks in women and their physicians. No studies exist yet in the United States in RA ascertaining patient-PHCP awareness of CVR,
Exploratory Analysis: Patient and PHCP correlates of CVRS and changes in CVRS in RA; Change in PHCPs CVRA	CVRS and changes in CVRS, Change in CVRA for PHCPs	Modifiable patient and PHCP correlates of CVRS and changes in CVRS would be identified. PHCP CVRA is modifiable.	Predictors of CVRS or change in CVRS will allow evidence based development of targeted strategies for patient and PHCP to improve CVRS in RA for future. Improvement in CVRA in PHCP will help facilitate further studies, interventions, and PQRI incentives

CVRA*: Eighteen modifiable and non-modifiable traditional CVR being assessed are* (a) Fifteen Non-modifiable and modifiable CVR: Age, Male gender, Postmenopausal status, Ethnicity, Family history of premature CVD (in father at age <55 yrs, or mother at age <65 years), smoking, dyslipidemia, hypertension, physical inactivity, obesity (>20% over ideal body weight), diabetes, stress, excessive alcohol, autoimmune diseases (e.g. RA), steroids, and (b) three RA-specific (Disease activity, duration, use of steroids).

CVRS: Checklist used to assess CVRS will include only primary CVR factors, and these will include elicitation of history of diabetes (if present, glycosylated hemoglobin annually in diabetics), dyslipidemia (if present, lipid panel in past one year), hypertension (if present, control of blood pressure in past one year), rheumatoid arthritis (Steroids, lipid panel in past one year), smoking (if present, education for cessation in past one year), poor activity level (if present, education on exercise in past one year), obesity (if present, BMI and/or weight loss education documentation in past one year), family history of CVD.

Data Collection: All consecutive patients with a diagnosis of RA seen in the Rheumatology clinics will be sought for participation. Inclusion criteria: A. *RA patients*: Adult men and women

meeting the following criteria (i) Diagnosed with RA with following criteria: Inflammatory symmetric polyarthritis of ≥6 weeks, with physician documented synovitis in medical records (past or current) consistent with RA, with or without rheumatoid factor, anti cyclic citrullinated peptide or radiologic evidence of RA. Exclusion of another etiology for above. (ii) Receipt of care by rheumatologist at either RUMC or JSH. This will allow us access to full medical records to correctly gauge the prevalence of CVRS. (iii) Informed consent. *B. PHCP*: (i) Physicians providing primary care to the RA patients recruited for this study for the EI group. Definition of PHCP has been previously provided (section F), (ii) Informed consent (iii) Not providing PHCP to RA patients in the non-EI group.

I.2. *Methods: 1.* **Education intervention development phase:** The primary outcome of the intervention development phase will be patient-centered EI video and PHCP-centered education EI to increase CVRA in RA. The interdisciplinary study team will develop a multi-level web-based EI for CVRA targeted to RA patients and their PHCPs. This team will consist of 3-6 RA patients and the panel of experts in rheumatology, preventive cardiology/endocrinology, and experimental health and social psychology. **To improve overall RA patient outcomes, our educational approach for the web-based EI is specifically aimed at changing the knowledge, and thus health behaviors of RA patients and their PHCP.**

Educational Approach: In the **development of the web-based EI** (Table 1, Figure 1), we will utilize credible, useful, innovative educational platform and input from opinion leaders in the therapeutic areas. All educational content will be learner centric in approach, language and content (Table 2). Content appropriateness of the tailored intervention will be verified by the health experts. Processes of change will be focused on increasing RA patients or their PHCP CVRA in general and in RA, and increasing their awareness of the need for change. This 20-30 minute You Tube EI video will be developed using scientifically researched content (Table 2).

Table 2: Development of Content for Educational web-based Intervention

Audience	Major Areas in Content Develo	Key Features
Patients	1) What is CVD and CVD in USA	Definition of CVD, Leading cause of death
	2) CVD in Women	Leading cause of death in women
	3) Traditional CVR factors	Modifiable and Non Modifiable
	4) Autoimmune diseases and CV	American Heart Association Guidelines (AHA) for CVR in women.
	5) RA and CVD	Major cause of mortality in RA
	6) RA specific CVR factors	Disease activity, duration, medications
	7) Suggested CVRS applicable to	US preventive services task force guidelines, National Cholesterol Education Program guidelines, EULAR guidelines
	8) Patients role in CVRS	For traditional CVR factors, contact PHCP; For RA factors contact Rheumatologist
PHCP	1) CVD in USA	Burden of CVD in US
	2) CVD in Women	Morbidity and mortality with CVD among women, Under recognized
	3) Traditional CVR factors	Framingham Risk factors and calculations
	4) Autoimmune diseases and CV	American Heart Association Guidelines (AHA) for CVR in women, especially RA, Lupus and psoriatic arthritis. Suggested adjustment for RA
	5) RA and CVD	Review of evidence based literature for RA and CVD
	6) RA specific CVR factors	Review of literature on RA associated factors associated with CVD eg inflammation
	7) Suggested CVRS in RA	Gaps in CVRS in RA, US preventive services task force guidelines, National Cholesterol Education Program guidelines, EULAR guidelines
	8) PHCP role in CVRS	For traditional CVR factors, contact PHCP; For RA factors contact Rheumatologist, PQRI

The finalized EI will be pretested among 5-10 RA patients and Physicians. Table 3 summarizes the way the planned methods address the established needs or identified gaps.

Table 3: Approach to the needs and identified gaps in cardiovascular risk awareness.

Established Need/Gap	Type of need/ Gap	Adressal of need/Gap through this study
Women have unique CVD risk Factors	Knowledge	Autoimmunity eg RA is a risk factor for CVD in women. We would foster education about this among women with RA and their PHCP.
The death rates from CAD in US women 35-54 yrs of age are increasing	Knowledge, Performance	By educating RA patients and PHCP about RA and CVD risk, especially in women, we expect PHCP and patients to partner CVRS in RA women, and decrease mortality.
Major cause of mortality in RA is CVD	Knowledge, Performance	By educating RA patients-PHCP about RA and CVR, we expect thenm to partner to screen for CVR in RA , and decrease mortality. Also by documenting poor CVRA among RA Patients and physicians, guidelines could be developed to ascribe responsibility and develop quality improvement initiatitives through physician reimbursements.
Status of CVRS in RA is far from optimal, even in Medicare age group patients	Knowledge, Performance, Competence, Attitudes	By educating RA patients-PHCP about RA and CVR, we expect physicians-PHCP would partner to screen for CVR in RA , and decrease mortality. Also by documenting poor awareness about CVD risks among RA Patients and physicians, guidelines could be developed to ascribe responsibility and develop quality improvement initiatitives through physician reimbursements.
There is a lack of knowledge in general about CVD risks in women and their physicians	Knowledge, Performance, Competence,	By educating RA patients-PHCP about CVR in general, we expect physicians-PHCP would partner to screen for CVD risks , and decrease mortality.
Physicians providing care to RA patients may not be clear on whose responsibility it is to screen for CVD risk and/or treatment.	Knowledge, Performance, Competence, processes	Clear designation of rheumatologist to address RA specific CVD risk factors, while working collaboratively with the PHCP on adressal of traditional risk factors will be presented to the patient-PHCP dyad in the intervention. By documenting lack of understanding on percieved responsibility about CVRS among various physicians, guidelines could be developed to ascribe responsibility and develop quality improvement initiatitives through physician linked reimbursements.
No studies exist yet in the United States in RA ascertaining patient or physician CVRA, despite the documented increased risk of CVD in RA.	Processes	The study will fill in the gap by providing this data for USA, and hence help locate opportunities for improvement.
No educational interventions targeting patient-physician CVRA are yet available for RA patients.	Knowledge, Performance, Competence, processes	The study will help us understand if using the latest technology of you tube to deliver the active educational intervention can result in improvement in knowledge.

EI fidelity monitoring will be undertaken through following (a) Delivery of intervention and process: web system will track how long each participant (Patient or PHCP) stayed on to the web-based YouTube EI video, before moving on to the follow up 1 survey, (b) Receipt fidelity: performance of CVRA at follow up 1 for patients and PHCPs, and (c) Enactment fidelity: use of credibility survey (described later).

I. Pilot-testing phase procedures are summarized in Table 4 and figure 1.

Table 4: Study Procedures

Participant	Procedure	Baseline (Day 0)	FU 1 (Day 0)	FU 2 (2-3 month)	FU (1 Year)
Focus Group (RA) n=5	Informed Consent	√			
	Demographics	√			
	Interviews	√			
	CVR Survey	√			
	Honorarium ($25)	√			
Pretest (RA) n=10	Informed Consent	√			
	Demographics	√			
	You Tube Video	√			
	Interviews	√			
	CVR Survey	√			
	Honorarium ($25)	√			
RA patients n=150 (EI)	Informed Consent	√			
	Demographics	√			
	CVR Survey	√ (In person)	√ (In person)	√ (In person)	
	You Tube Video	√			
	Honorarium ($25)	√		√	
	Medical Chart	√			√
RA Patients n=150 (non EI)	Informed Consent	√			
	Demographics	√			
	CVR Survey	√ (In person)		√ (In person)	
	You Tube Video				
	Honorarium ($25)	√		√	
	Medical Chart Review	√			√
PHCP	Informed Consent	√			
n=50	Demographics	√			
	CVR Survey	√ (Email)	√ (Email)		
	You Tube Video	√			

Assessment of CVRA in Patients: After informed consent, each participant will be assigned a unique study number, which will be used to pair data from the pre- and post-intervention visits. Participants will be given an online survey to fill to assess their CVRA (*Baseline Patient survey*). A You Tube video will be shown to the patient on a tablet or a computer screen. The video recording will be of 20-30 minutes duration to avoid attention fatigue. Immediately after viewing the video, each patient will be given the CVRA online survey (*Follow up Patient survey 1*). An exit online credibility survey will be used to gather feedback on credibility (user-friendliness, content, understandability, and relevance), barriers experienced in using the web-based intervention and any suggestions (open-ended). To assess retention of knowledge, between 2-3 months after the baseline visit the second post-intervention assessment (*Follow up Patient survey 2*) using the same CVRA survey will be administered online. Follow up survey

2 will be paired data. Medical charts records will be reviewed to quantify prevalence of CVRS by PHCP (within one-year period preceding baseline visit) at baseline and one-year follow up visit. For patients whose PHCP is not within Rush University Medical Center or John H Stroger Hospital, we will contact their local PHCP to obtain their pertinent medical records to quantify prevalence of CVRS by PHCP (within one-year period preceding baseline visit) at baseline and one-year follow up visit. Study participants will be asked to provide informed consent to communicate with their PHCP and access to their medical records to allow for assessment of CVRS.

Assessment of CVRA in PHCPs: PHCPs will be contacted by email. Acceptance to proceed with the study online will be taken as informed consent. Online survey on their CVRA (*Baseline PHCP survey*) will be evaluated using case scenarios developed specifically for this purpose, followed by a You-Tube video developed using evidence based literature review, specially including autoimmune diseases and risk of CVD in women and RA. This will be developed at the level of the targeted audience and of 20-30 minutes duration. They will then be prompted to take the same case scenario based survey immediately to assess their CVRA (*Follow up PHCP survey 1*). An exit online credibility survey will be used to gather feedback on credibility (user-friendliness, content, understandability, and relevance), barriers experienced in using the web-based intervention and any suggestions (open-ended).

I.3.Tools:

Survey to assess CVRA: The survey will include the following components:

1. The content of Patient surveys: Brief survey to collect demographic and self reported past medical history, family history, Social history and current medications, current weight and height. This will be administered to RA.

Perception of risk of heart disease scale (PRHDS) (8), Heart Disease Fact Questionnaire (HDFQ)(24) will be modified to include some items on autoimmune diseases (including RA).Relevant components of the Behavioral Risk Factor Surveillance System (BRFSS) 2013 survey from US Centers for Disease Control 2013 (22). This will include sections and modules on hypertension awareness (2 items), cholesterol awareness (3 items), chronic health conditions (12 items), tobacco use (5 items), pre diabetes and diabetes (10 items), cardiovascular health (7 items), Mental Illness and Stigma (10 items) and Emotional Support and life satisfaction (2 items).

2. The content of PHCP surveys: A survey to assess CVRA in PHCPs will be developed. This survey development will be guided by the co-investigators and a questionnaire adapted from BRFSS and National Health and Nutrition Examination Survey (21) that was used previously in a similar study (8). The survey will be modified to include questions about CVRA in women and in autoimmune diseases. In addition, five hypothetical case scenarios will be created with various combinations of CVR in patients with and without autoimmune disease, and PHCP will be asked to select the CVRS indicated and strategies to optimize the patient's individual CVD risks.

The finalized surveys used for CVRA will be pretested among 5-10 RA patients and Physicians.

I.4. Incentives: For the participating RA, a $50 honorarium will be provided at baseline and follow up visit (Table 4).

I.6. Data: *Patient*: Demographic (age, gender, ethnicity), Socio-economic status (education) and RA pertinent data (duration, presence of Rheumatoid factor and/or anti cyclic citrullinated peptide, bony erosions, medications (including steroids and biologics)). Self reported CVRA (Overall, Traditional and RA) will be assessed at baseline, immediately after viewing the video (follow up 1), and after 2-3 months (follow up 2).

PHCP: Demographic (age, gender, ethnicity), type of physicians (Internal Medicine, Family practice, Rheumatologist), years since completion of residency in Internal Medicine or Family Practice, years since board certification, currently board certification status, setting of practice (academic, community or private practice), rank (if any), approximate number of RA patients seen yearly. Self reported CVRA (Overall, Traditional and RA) will be assessed at baseline, immediately after viewing the video (follow up 1), and after 2-3 months (follow up 2).

Rates for CVRS at baseline and one year later for all RA patients (with and without EI) will be determined using a checklist.

I.7. Proposed Analyses: (Table 1) SPSS software will be used for data analyses. Data distribution will be evaluated. Standard descriptive statistics will be used to analyze (a) patient characteristics: demographics, socioeconomic status, RA disease pertinent information; and (b) PHCP characteristics: demographics, type of physician and practice, board certification status, and annual count of RA patients. Comparison between demographics and disease characteristics of RA patients with and without EI will be conducted using chi square and t test analysis.

I. Intervention development phase

Aim 1. Qualitative analyses will be used to gather data about the content, relevance, ease-of-use, credibility and delivery of the educational materials. This data will be used to refine the intervention. Descriptive EI fidelity monitoring data analysis will be undertaken (mean duration (Patient or PHCP) engagement YouTube EI video, completion of CVRA at follow up 1 for patients and PHCPs, and credibility survey data). Latter data will evaluate the need, ease, content and understandability, relevance of the EI.

Engagement of audience will be judged through observation of body language RA patients during the entire study. In addition, feedback on the credibility of the intervention is being sought from both the patients and PHCP to establish its user-friendliness, content, relevance and understandability. Moreover, special efforts have been undertaken to limit survey burden and limit the duration of the EI to allow for full engagement of the participants. We feel that the technology platform being used for the intervention, brevity, its speed and ease will allow for greater audience engagement.

II. Pilot-testing phase.

Aim 2A. To compare changes in CVRA in RA patients (a) after web-based EI. We hypothesize that 20% increase in overall CVRA (measured using standardized survey) at 2-3 months post intervention; (b) with and without web-based EI. We hypothesize significantly greater improvement in overall CVRA among RA patients with EI as compared to non EI group, at 2-3 months.

For patients (a) Overall CVRA (ORA), (b) Traditional CVR awareness (TRA) (c) RA CVR awareness (RARA) will be calculated. Awareness of all 18 CVR being tested (listed in section 1) will denote 100% CVR awareness. To score ORA, patient's correct responses denoting awareness to each of the 18 CVR being tested will be calculated in percentage of total responses. Domain-specific CVR awareness for traditional CVR (TRA) and RA (RARA) will be scored separately using the same strategy.

Paired t tests to compare pre and post (Follow up 2) patient overall CVRA for our primary outcome of interest will be performed. Effect size of gains in overall CVRA for RA patients after EI (Follow up survey 2 and baseline) will be calculated. We will then compare percent change in overall CVRA rates (between baseline and follow up 2) using chi square analysis, among EI and non-EI patients with RA. A p value of ≤ 0.05 will be considered significant on two tailed tests.

Aim 2B. To explore changes in cardiovascular risk screening (CVRS) at the primary health care visits among RA patients with and without EI.

The medical records of RA patients with and without EI will be reviewed in electronic medical record, and analyzed using standardized checklist to assess the prevalence of CVRS and CVD risk reduction plan (meaningful use). Changes in CVRS rates among EI and non EI groups will be calculated, and compared using chi square analysis. A p value of ≤ 0.05 will be considered significant on two tailed tests.

Exploratory analysis on improvement in PHCP overall CVRA using analysis similar to those discussed for aim 2a will be undertaken, a post hoc power analysis and effect size will be obtained. In addition exploratory univariate and multivariate logistic or linear regression analysis for patient and PHCP correlates of CVRS (baseline) and change in CVRS will be performed. Improvements in Traditional and RA-specific CVRA among RA and PHCPs will be assessed.

J. Dissemination plan: The first step in disseminating outcomes will be to share the results of the study with the participants of the study, RA patients and their PHCP.

Next, the results of the study would be submitted for presentation at a regional or National conference pertinent to primary care providers, rheumatology and preventive cardiology audience. Options include American College of Physicians, Quality improvement conferences, American College of Rheumatology, American Heart Association and Women's health Conferences. Preparation and publication of the manuscript will be the pivotal step in disseminating the outcomes. Potential target journals for submission could be from Internal Medicine, Preventive Medicine, Cardiovascular, Outcomes or Rheumatology based. General Medicine Journals targeted could include Journal of American Medical Association, Lancet,

while cardiology journal circulation may be of interest. Rheumatology journals of interest would include *Journal of Rheumatology, Arthritis Care and Research, Annals of Rheumatic Diseases* or *Arthritis Research & Therapy.* Publication of data may encourage discussion or statement from the National organizations with strategies to increase CVD risk awareness and screening. Continuing medical education activities could be built based on the results dissemination.

We feel that web-based EI could reach many more RA patients in a timely fashion without using many resources. In addition, this strategy could provide patients ease, flexibility and privacy with their educational module administration. National organizations such as the Arthritis Foundation and with support of such web-based resources through unrestricted educational funds could further mobilize this intervention to across the globe.

K. Project Timeline: Major study processes and data accrual with corresponding anticipated timeline are shown below in figure 1. Deliverables and timelines for entire project are shown in Table 5 below.

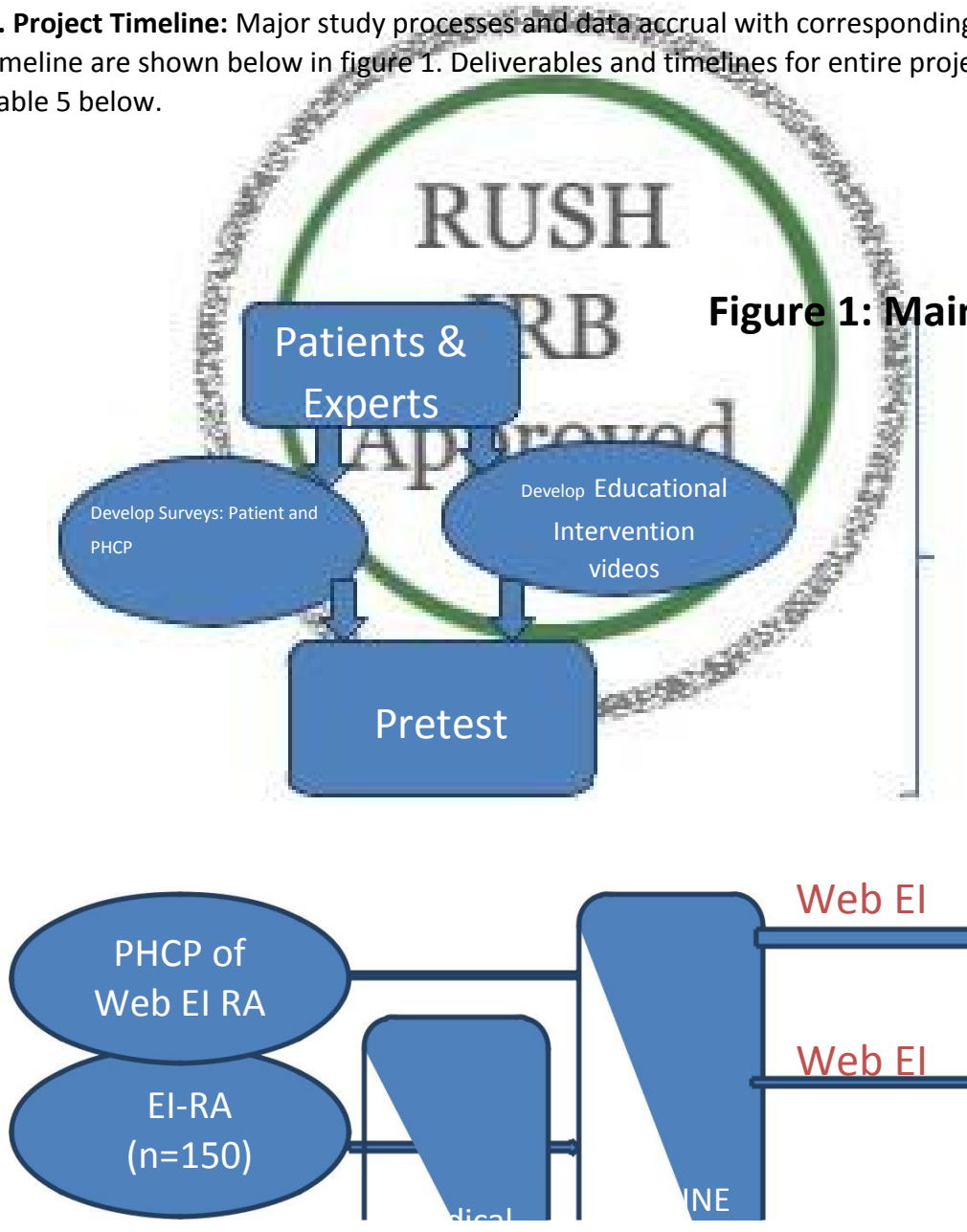

Figure 1: Main processes and data

1/2015-6/30/15

Table 5: Project Timeline and Deliverables		
Deliverable	**Tasks**	**Date**
Institutional Review Board	Regulatory documents, HIPPA etc for RUMC and JSH	1/1/2015-3/1/2015
Develop Study Documents	Defining processes, training of research assistant, study cordinator, incentives/parking organization	1/30/2015-3/1/2015
CVR Surveys	Modify the existent survey tools, Obtain permission for use of surveys, Collaborative meetings to discuss content and format, Develop Case Scenarios for Physicians, Reviews, Refinement , Pretest surveys	3/1/2015 to 5/30/2015
You tube Educational module-Pat	Focus group, gather pertinent content, parse information, develop transcripts, assess understandibility level, schedule recording, recording, editing, pretesting, refining	6/30/2015
You tube Educational module-Phy	Gather pertinent content, parse information, develop transcript, assess reading/understandibility level, schedule recording, recording, editing, pretesting, refining	6/30/2015
RA and PHCP recruitment status	At RUMC and JSH	7/1/2015 to 7/1/2016
Medical Chart reviews for RA patients Baseline	Identification of PHCP, review of records, data entry	7/1/2015 to 7/30/2016
Identification of PHCP, review of records, data entry-One year Follow up	Identification of PHCP, review of records, data entry	7/1/2016 to 8/15/2017
Data Management	Data entry, data cleaning, simple analysis	7/15/2015 to 10/15/2017
Simple Results	Statistical analysis, interpretation	11/15/2017
Presentation of Results	Abstracts writing, submission and presentation	11/15/2017 to 1/1/2018
Manuscript	Writing of manuscript, submission	12/30/2017 to 3/31/2018

L. Additional Information: Abbreviations glossary is provided below.

RA (Rheumatoid Arthritis); PHCP (Primary health care provider); EI (Educational intervention); CVD (Cardio-vascular disease); CVR (Cardiovascular risk); CAD (Coronary artery disease); CVRA (Cardiovascular risk awareness); CVRS (Cardiovascular risk screening);RUMC (Rush University Medical Center), JSH (John H Stroger Hospital); PI (Primary investigator); Co-I (Co investigator); NIH (National Institute of Health).

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