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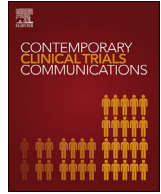
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A multi-modal intervention for Activating Patients at Risk for Osteoporosis (APROPOS): Rationale, design, and uptake of online study intervention material



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ABSTRACT

Objective: To develop an innovative and effective educational intervention to inform patients about the need for osteoporosis treatment and to determine factors associated with its online uptake.

Methods: Postmenopausal women with a prior fracture and not currently using osteoporosis therapy were eligible to be included in the Activating Patients at Risk for Osteoporosis (APROPOS). Four nominal groups with a total of 18 racially/ethnically diverse women identified osteoporosis treatment barriers. We used the Information, Motivation, Behavior Skills conceptual model to develop a direct-to-patient intervention to mitigate potentially modifiable barriers to osteoporosis therapy. The intervention included videos tailored by participants' race/ethnicity and their survey responses: ranked barriers to osteoporosis treatment, deduced barriers to treatment, readiness to behavior change, and osteoporosis treatment history. Videos consisted of "storytelling" narratives, based on osteoporosis patient experiences and portrayed by actresses of patient-identified race/ethnicity. We also delivered personalized brief phone calls followed by an interactive voice-response phone messages aimed to promote uptake of the videos.

Abbreviations: BMD, bone mineral density; GI, gastrointestinal; GLOW, Global Longitudinal Study of Osteoporosis in Women; HIV, human immunodeficiency virus; IMB, information, motivation, behavior; IVR, interactive voice-response; NG, nominal group; NHANES, National Health and Nutrition Examination Study; PAM, Patient Activation Measure; PAPM, Precaution Adoption Process Model; ONJ, osteonecrosis of the jaw.

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Results: To address the factors associated with online intervention uptake, we focused on participants assigned to the intervention arm ($n = 1342$). These participants were 92.9% Caucasian, with a mean (SD) age 74.9 (8.0) years and the majority (77.7%) had some college education. Preference for natural treatments was the barrier ranked #1 by most ($n = 130$; 27%), while concern about osteonecrosis of the jaw was the most frequently reported barrier (at any level; $n = 322$; 67%). Overall, 28.1% ($n = 377$) of participants in the intervention group accessed the videos online. After adjusting for relevant covariates, the participants who provided an email address had 6.07 (95% CI 4.53–8.14) higher adjusted odds of accessing their online videos compared to those who did not.

Conclusion: We developed and implemented a novel tailored multi-modal intervention to improve initiation of osteoporosis therapy. An email address provided on the survey was the most important factor independently associated with accessing the intervention online. The design and uptake of this intervention may have implications for future studies in osteoporosis or other chronic diseases.

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1. Introduction

Osteoporosis contributes to more than 2 million fractures each year in the United States (U.S.) and is responsible for \$19 billion costs annually [1]. Despite robust evidence supporting national guidelines for various medications to significantly reduce fracture risk among persons with prior fractures [2–7], only about 1 in 5 older women with a prior fracture receives osteoporosis evaluation and fewer than half of these women receive a prescription for osteoporosis therapy [8]. Even after receiving a prescription, only 60–70% of patients initiate osteoporosis treatment [9,10]. There is an urgent need for interventions aimed at increasing osteoporosis therapy initiation for patients at high fracture risk.

The majority of interventions used to improve uptake of osteoporosis treatment have targeted health care providers rather than patients [11–18]. The sparsity of patient activation interventions in the osteoporosis field is surprising given the reported successes of these methods in improving outcomes including improved patient knowledge [19–21], calcium intake [22], physical activity [23], and bone mineral density (BMD) testing [24]. Given the major societal trend for increased patient involvement in shared decision making [25,26], patient-based interventions are often more pragmatic and cost effective than more traditional provider-based interventions, though evidence of effectiveness is largely lacking [27].

From the patient perspective, the causes of non-initiation of osteoporosis therapy include concerns about medication side effects, costs, polypharmacy, and perceptions of limited efficacy [10,28–31]. According to the Information, Motivation and Behavioral Skills model (IMB) [32], when people are well-informed, motivated to act, and possess the skills and confidence to take action, they are more likely to initiate and maintain health-promoting behaviors that produce positive outcomes. The IMB model has been applied successfully to a variety of health behaviors, including changing risk behavior [32] and adherence to medications [33,34] for human immunodeficiency virus/acquired immunodeficiency syndrome and breast self-examination [35].

Internet-based communication technologies, with their advantageous cost effectiveness and ability to efficiently reach a large number of people [36], can help address the existing gap between guidelines and clinical practice for chronic conditions, such as osteoporosis. Online interventions can be tailored, are readily scalable and convenient, and are easily accessible to those with internet access, thus making them ideal venues for delivery of self-care and behavior-change programs for a large and rapidly growing segment of society that includes older adults [37]. This manuscript details formative qualitative work and the development and uptake of our online-delivered, individually-tailored, video-based, and

multi-modal intervention within an ongoing cohort study of osteoporosis in older women.

2. Methods

We used the IMB model conceptual framework to develop a direct-to-patient, tailored intervention aimed at increasing the initiation of osteoporosis medications in women at high risk for fractures. We used qualitative methods to elicit information, motivation, and behavioral skills important to initiating osteoporosis treatment. Next, we designed a video-based, individually-tailored intervention to help mitigate potentially modifiable barriers to osteoporosis therapy. The intervention was delivered online and by DVD mailings to women aged 55 and older who had a history of fractures. We also conducted personalized phone calls followed by interactive voice-response (IVR) messages to promote intervention uptake.

2.1. Study population

The Global Longitudinal Study of Osteoporosis in Women (GLOW) cohort is an international prospective, longitudinal, observational study of women 55 years of age and older. Data on osteoporosis risk factors, treatment approaches, patient attitudes, beliefs and behaviors related to osteoporosis, and fracture outcomes have been collected for up to 5 years through annual patient questionnaires from 2005 to 2011. GLOW includes 60,393 women (28,170 in the US) recruited from 723 physicians (298 in the US) [38]. We sent survey materials to the subset of GLOW participants from the 7 GLOW U.S. sites (Birmingham, AL; Los Angeles, CA; Worcester, MA; New York, NY; Cincinnati, OH; Pittsburgh, PA; Seattle, WA) at high risk for future fracture as determined by: (1) reported history of a prior fracture after age 45 in previous GLOW surveys, and (2) no reported current use of osteoporosis medication with the exception of estrogen treatments. This sub-cohort of GLOW participants ($n = 2684$) formed the Activating Patients at Risk for Osteoporosis (APROPOS) study population. The APROPOS baseline survey was sent to 4928 GLOW participants who had a fracture history. We received 3226 completed surveys (64% response rate), of which 2684 met eligibility criteria. These women were randomized to receive intervention materials (intervention group, $n = 1342$) or usual care (no intervention and routine medical care per their existing health care providers, $n = 1342$). The intervention was developed as part of a randomized clinical trial (ClinicalTrials.gov identifier NCT01907269) and was provided free of charge to participants. This report focuses on the intervention development and factors associated with the uptake of our online intervention.

2.2. Intervention development (Fig. 1)

2.2.1. Identification and assessment of barriers to osteoporosis treatment (Fig. 1a)

Potential barriers to osteoporosis treatment were identified and prioritized using a nominal group (NG) technique, which allowed participation from all group members, and promoted group-decision making [39]. We conducted 4 nominal groups (2 each in Birmingham, AL and Los Angeles, CA) with ethnically and racially diverse postmenopausal women with an overall history of osteoporotic fracture not currently receiving osteoporosis treatment (total $n = 18$). Two groups had never received medication and women within the other two groups had started medication but stopped. We asked each woman to individually identify barriers to osteoporosis medication use. Each group generated a list of barriers and, subsequently, each participant voted on her top 3 barriers. This resulted in a rank ordered list of 29 potential barriers to osteoporosis treatment. We combined responses with similar wording/meaning, thereby reducing the list to 25 (Appendix A). We reviewed and grouped barriers by common themes (e.g., preferences for dietary supplements rather than prescription medications, etc.) and identified those that could potentially be mitigated by a video-based intervention. For example, we obtained investigator group consensus that information and patient testimonials provided by a video could potentially address participants' concerns about osteonecrosis of the jaw (ONJ), but would be less successful in addressing barriers related to medication costs. This procedure generated a list of seven potentially modifiable barriers.

2.2.2. Baseline survey development

Based on prior GLOW surveys [40], we created a survey to assess health history, use of osteoporosis prescription medication, fracture history, use of dietary supplements, perceived ability to communicate with a health care provider about bone health [41], health literacy [42], preferences for sources of health information, modified patient activation measure (PAM) [43], as well as items from the Patients' views about osteoporosis and use of therapy scale [10]. We also assessed readiness to behavior change using a modified form of the Weinstein Precaution Adoption Process Model (PAPM) [44]. We defined pre-contemplative participants, representing the individuals in the unaware and unengaged stages of PAPM, as those that had no intent of initiating prescription treatment for osteoporosis. Contemplative participants, representing those in the undecided, decided not to act, and decided to act stages of PAPM, were defined as actively considering initiating prescription treatment for osteoporosis [45].

Guided by potentially modifiable barriers identified from the NGs, we surveyed all randomized APROPOS study participants ($n = 2684$) and asked them to rank up to three of the eight potentially modifiable barriers to osteoporosis treatment. We mailed this survey to eligible women enrolled in the GLOW US cohort, aged 55 and older and with self-reported history of fracture.

2.2.3. Video development and content

We next developed an individualized direct-to-patient, video-based intervention grounded in narrative communication ("story-telling") [46,47] that consisted of video segments to address the barriers ranked by participants. First, we used the constructs of the IMB model [48] to frame each potentially modifiable barrier. Then, we developed an outline for video materials including the barrier/treatment concern, how to overcome the problem, and whether a patient actor, health care professional, or both would be featured addressing the problem. Additional outlines were developed for general osteoporosis risk awareness and communication of bone health issues with health care providers.

Using the outlines as a guide, we performed structured interviews with osteoporosis patients ($n = 8$) receiving care at the University of Alabama at Birmingham. The interviews captured each patient's experiences with her bone health including: concerns about starting and taking prescription medication; concerns about fractures and their impact on daily life; and skills used for talking with their health care team about improving bone health. We reviewed and divided interview transcripts into discrete story units focused on a single message to create scripts for the videos. When needed, parts from multiple patients' interviews were combined to deliver a single coherent message addressing a specific barrier to osteoporosis treatment. If the structured patient interviews did not provide sufficient information to address one barrier, a script for a health care provider actor was created and used in the video. The role of the health care provider scripts was to reinforce and supplement patient stories.

2.2.4. Tailoring of the intervention

We tailored our intervention based on (1) the survey responses and (2) participant's reported race/ethnicity. For the first layer of intervention tailoring, four mutually exclusive groups received tailored video assignments based on their survey responses: *Group I*: individuals who ranked or identified barriers to osteoporosis treatment, *Group II*: individuals who did not rank barriers, but where barriers could be deduced based on responses to survey materials (i.e. physician recommended break from osteoporosis medications, more than 5 years of treatment, concerns about long-term adverse events as assessed by the Patients' Views about Osteoporosis and Use of Therapy scale [10]), *Group III*: individuals who did not identify barriers to treatment but for whom readiness to behavior change using a modified form of Weinstein PAPM was available, *Group IV*: Individuals for whom only the osteoporosis treatment history was available and who did not provide answers to the survey items on barriers to osteoporosis treatment or readiness to behavior change.

Those participants who did not rank barriers or identify other reasons for not taking osteoporosis medications on our survey (*Group III*) received videos tailored to their level of readiness for behavior change based on their responses to items in the Weinstein PAPM [44,45]. To determine the most appropriate video materials to provide these participants, we pilot tested a series of general osteoporosis knowledge videos with pre-contemplative ($n = 6$) and contemplative ($n = 6$) women in Los Angeles, CA and Birmingham, AL. These videos focused on osteoporosis risk awareness, impact of a fracture on others, general concerns about medications, available treatment options, and the rationale behind why dietary supplements alone are not enough for bone health. Using a 5-point Likert scale with 1 indicating very unlikely and 5 indicating very likely, we asked the pilot test participants to rate each video on its ability to promote behavior change (e.g., "video made me want to talk to my health care provider about my bone health" and "video made me want to start a medicine for my bones") and provided the videos with the highest rankings for pre-contemplative and contemplative women who received the intervention materials.

For the second layer of tailoring, we produced video segments with patients of the same ethnicity/race as self-identified by the participants (e.g., patient actors from the same racial (Caucasian and African American) and ethnic (Hispanic and non-Hispanic) backgrounds). For the patient scripts, we recorded five standardized patient actresses (2 Caucasian, 2 African American, 1 Hispanic American) and for health care provider script, one Caucasian, female nurse educator. We assigned a Hispanic American actress to participants who self-identified as being of Hispanic/Latino origin or descent regardless of whether they later indicated they were Caucasian, African American, or other. Participants who self-

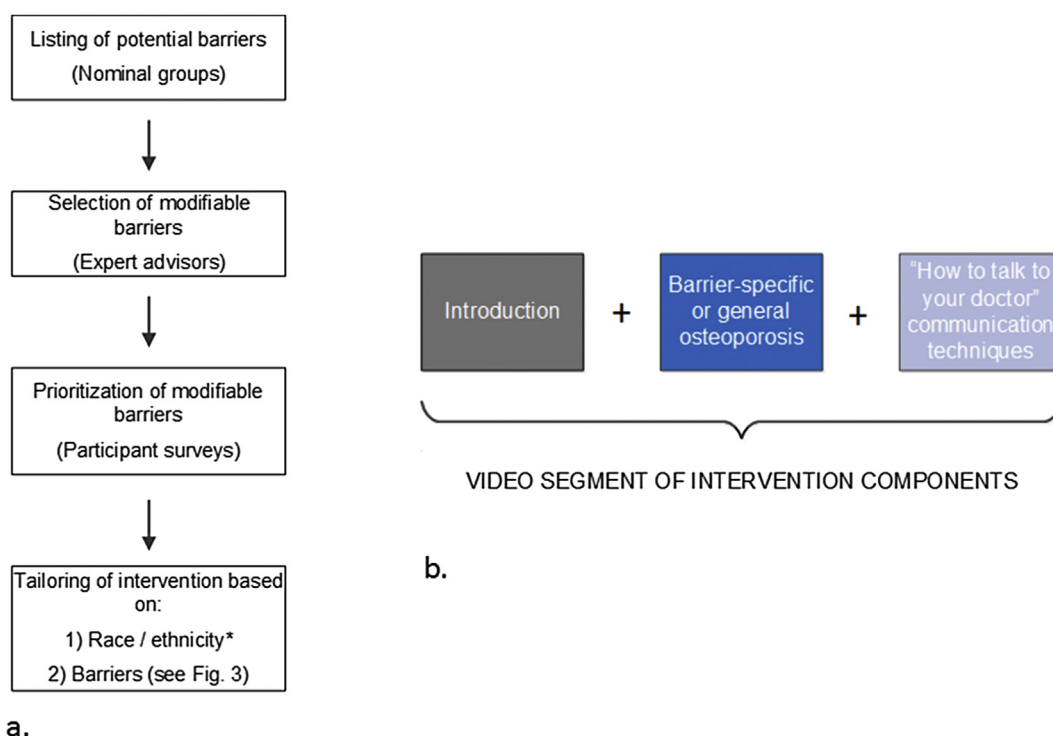


Fig. 1. Intervention design for women in the Activating Patients at Risk for Osteoporosis (APROPOS) Study. (a) Nominal groups were used to generate a list of barriers (Appendix A) that experts reduced to those potentially modifiable by an intervention. Potentially modifiable barriers were ranked by participants on surveys and these responses were used to tailor the first layer of the intervention, followed by the second layer of tailoring (self-identified race/ethnicity) (b). Participants received video segments with three components: an introduction, videos tailored based on participant ranked specific barriers or general osteoporosis treatment barriers, and a video on “How to talk to your doctor” communication techniques *Women who self-identified other than Caucasian, African American, and/or Hispanic comprised less than 2% of our intervention population and received intervention videos with Caucasian female educators and patient actresses.

identified their race as Asian or other (<2% of our intervention population), received videos with a Caucasian actress.

2.2.5. Video intervention content development

The video intervention (see Fig. 1b) had 3 components. The first component included an *introduction video* explaining why the participant was receiving the material. The second component included either: 2a) up to 3 *barrier-specific videos* (for participants who reported ≤ 3 barriers) or *videos addressing the most commonly reported and highest ranked barriers* (for the participants that ranked ≥ 4 barriers), or 2b) up to two *videos focused on osteoporosis* (for those who did not rank barriers). The third component included a *video on “how to talk to your doctor” communication techniques* that patients could use to discuss osteoporosis treatment with their health care professional for all participants [49].

To maximize the relevance of the video program to individual participants and ensure that participants were not overwhelmed by the extent/length of the educational materials received, the intervention was customized to address their 3 highest ranked barriers reported on baseline surveys by combining multiple video segments into a single video. Importantly, the survey did not formally restrict participants to selecting only 3 barriers, nor to ranking identified barriers as the top 3 (i.e. a participant could identify 3 barriers and rank these all as #1). In those instances where participants did not clearly rank barriers as instructed, we adhered to the rankings as closely as possible for selecting the intervention materials.

Participants assigned to Group III intervention materials (i.e. those who did not rank barriers to osteoporosis treatment and for whom other reasons for not taking osteoporosis medications were

not available) were provided with videos based on their answers to the modified form of the Weinstein PAMP. Contemplative participants were provided videos on *“treatment options”* and *“supplements are not enough”*, while the pre-contemplative participants were provided videos on *“osteoporosis risk awareness”*.

Finally, participants who failed to identify any barriers to treatment and for whom we were unable to determine the level of readiness to behavior change (Group IV) were assigned videos on *“osteoporosis treatment options”* and *“supplements are not enough”* if they indicated prior osteoporosis treatment or a general *“osteoporosis risk awareness”* video if they had not reported prior osteoporosis treatment.

The contractor cost for intervention development (video and DVD production, website development, and internet domain) was \$68,036. This estimate excludes ongoing maintenance cost of the intervention or investigator and staff costs and time devoted to the development and implementation of the intervention which were supported by a 5-year NIH grant, making it difficult to assign cost to these items.

2.3. Intervention delivery/implementation (Fig. 2)

We delivered the video intervention free of charge to participants in the intervention arm online and through DVD mailings. For participants in the intervention arm, we initially mailed an introductory letter containing an overview of the video program, instructions for accessing the materials, a web link, and a code that enabled participants to access their personalized video program online. An email with content similar to the introductory letter was sent to all participants who provided an email address on the

baseline survey 2–3 days after the introductory letter. The email contained a hyperlink directing the participant to her personalized video program. As part of the personalized video intervention, we also included a “Talking Points Card” containing a set of questions about bone health that the participants were encouraged to discuss with their health care provider. Approximately one week after the initial letter and email (if applicable) were sent, we mailed participants in the intervention arm a DVD with their personalized video program (and a DVD player for those who did not report having

one), a second copy of the introduction letter, and a hard copy of the “Talking Points Card”.

One week later, a project staff member called the study participants who were sent the intervention materials and who had provided phone numbers (termed a “warm handoff”), but who had not viewed videos online. The goal of this phone call was to further introduce the video program intervention thereby increasing participant engagement. During this warm handoff call, we informed participants of the reason for the intervention materials,

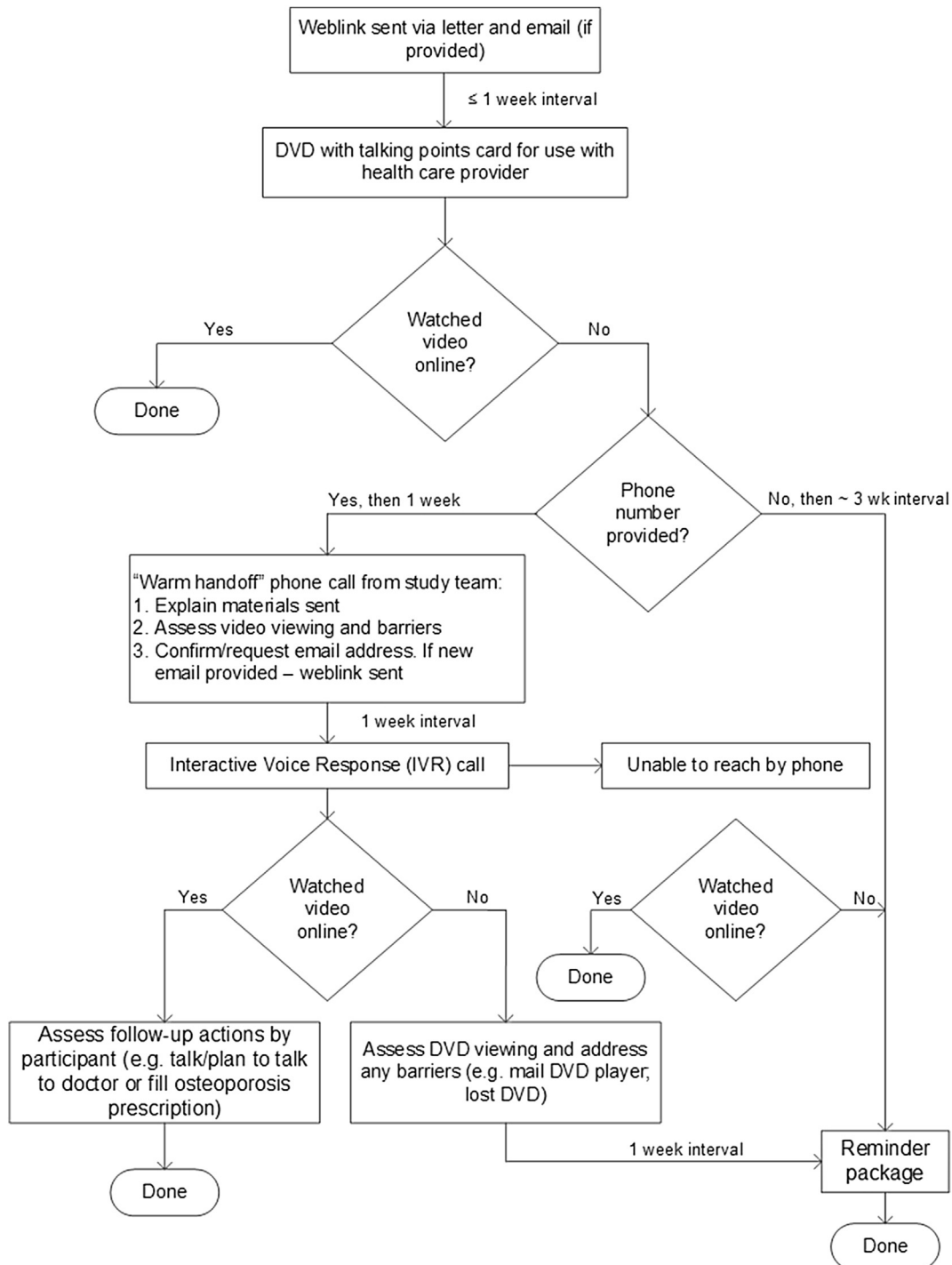


Fig. 2. Intervention deployment workflow for women in the Activating Patients at Risk for Osteoporosis (APROPOS) Study. IVR, interactive voice-response.

attempted to identify and address any barriers to watching the videos (e.g., sending a DVD player), and confirmed or requested an email address. Participants who provided an email during the warm handoff call were subsequently sent an email with the web link and code to access their personalized video program. Approximately 1–2 weeks after the warm handoff phone call, we used interactive voice response (IVR) technology to deliver an automated phone call to the participants in the intervention arm who had not yet viewed the videos online for the purpose of inquiring whether the materials had been viewed and if they had experienced barriers to watching the videos.

Approximately 4 weeks after the introductory letter, participants who could not be contacted by phone or who had not provided a telephone number on the baseline survey, or who had not viewed the website were mailed a reminder package. This package contained a copy of the introductory letter detailing the instructions on how to access the video program online, and included the web address linked to the personalized code-accessed video program, as well as another DVD with the individualized video intervention.

2.4. Statistical analysis overview

We used descriptive statistics to characterize the population recruited to the intervention arm. Means (SD) were calculated for normally distributed continuous variables and proportions were used to describe categorical variables. For this descriptive study, primary dependent variable was defined as uptake of the intervention and was operationalized by assessing participants' successfully logging onto their own personal website within 60 days after initial contact by email. We chose this time cut point as a pragmatic data lock for our intervention uptake because during this timeframe more than 95% of the individuals had logged onto their personalized website. The proportion of participants logging on to the website was reported overall by sociodemographic subgroups as well as by type of contact provided (e.g., email only, phone only, phone and email, and no email/no phone). Bivariate tests (e.g., student t tests and chi square tests) and stepwise multivariable logistic regression were used to evaluate differences in uptake of the intervention by sociodemographic characteristics and type of contact. The following covariates were considered in the multivariable analyses: age, race/ethnicity, education, study site, health literacy, self-reported history of depression, readiness to behavior change, and whether the participants expressed concerns about osteoporosis. We report both unadjusted and adjusted odds ratios (ORs/aORs), respectively, and corresponding 95% confidence intervals (CIs) to express the strength of the association between having an email address and interacting with the website. For stepwise regression analyses, we entered variables of interest into the model if the p values were less than 0.1 and retained in the final model only significant variables with p values less than 0.05 or those variables considered biologically important. All analyses were conducted using SAS v9.3 (Enterprise Guide v4.3) package.

3. Results

To address the factors associated with online intervention uptake, we focused our analysis on participants assigned to the intervention arm (n = 1342). Observational data for our population was normally distributed as measured with Quantile-Quantile plots. These participants were 92.9% Caucasian, with a mean (SD) age of 74.9 (8.0) years and the majority (77.7%) had some college education. Overall, 28% (377 out of 1342) of women randomized to receive the intervention videos logged on to the educational materials online within 60 days after the initial mailing of the

Table 1

Demographic characteristics of respondents (N = 1342) randomized to the intervention, divided by website activity.^a

	Logged onto website within 60 days		p-value
	Yes n = 377	No n = 965	
Age, mean (SD), years	72.9(7.0)	75.7(8.2)	<0.0001
Age ¹			
60–69	132(35.0%)	248(25.7%)	<0.0001
70–79	172(45.6%)	393(40.7%)	
80–89	68(18.0%)	281(29.1%)	
90+	5(1.3%)	43(4.5%)	
Race/ethnicity			
Caucasian	363(96.3%)	884(91.6%)	0.0027
Other	14(3.7%)	81(8.4%)	
Recruitment site			
Birmingham, AL	44(11.7%)	162(16.8%)	0.017
Cincinnati, OH	35(9.3%)	110(11.4%)	
Los Angeles, CA	46(12.2%)	79(8.2%)	
New York, NY	52(13.8%)	115(11.9%)	
Pittsburgh, PA	55(14.6%)	141(14.6%)	
Seattle, WA	82(21.8%)	167(17.3%)	
Worcester, MA	63(16.7%)	191(19.8%)	
Education ²			
Some high school or less	3(0.8%)	37(3.9%)	<0.0001
High school graduate	41(11.0%)	214(22.5%)	
Some college or more	329(88.2%)	701(73.6%)	
Concerned about osteoporosis ³	215(61.6%)	495(57.3%)	0.1511
No past treatment for osteoporosis ⁴	105(28.5%)	344(38.0%)	0.0013
Comorbidities			
Depression ⁵	70(19.4%)	202(21.9%)	0.3411
Readiness to behavior change ^{b, 6}			
Pre-contemplative	239(74.2%)	583(75.3%)	0.7018
Contemplative	83(25.8%)	191(24.7%)	
Phone/email provided			
Phone and email	219(58.1%)	253(26.2%)	<0.0001
Email only	77(20.4%)	92(9.5%)	
Phone only	53(14.1%)	374(38.8%)	
Neither	28(7.4%)	246(25.5%)	
Health literacy			
Adequate	350(94.1%)	794(84.8%)	<0.0001
Inadequate	22(5.9%)	142(15.2%)	

¹missing for 2 persons, ²missing for 17, ³missing for 130, ⁴missing for 67, ⁵missing for 58, ⁶missing for 246.

^a For categorical variables data is presented as N(%).

^b readiness to behavior change assessed with a modified form of the Weinstein Precaution Adoption Process Model (PAPM).

intervention materials (Table 1). Demographic characteristics of women randomized to the intervention arm, stratified by whether or not they interacted with the video intervention materials are presented in Table 1. Of the women randomized to the intervention arm, 860 did not rank any barriers to osteoporosis treatment (64.1%), 364 ranked 3 or fewer barriers (27.1%), and 118 ranked 4 or more barriers (8.8%) (Table 2). Preference for “natural treatments” was ranked highest by 130 women on the baseline survey, while ONJ was the most frequently endorsed barrier overall (n = 322).

A total of 1342 women were mailed the introductory letter and intervention materials via email and standard mail. The intervention was tailored based on the participants' responses to the survey assessing their barriers to osteoporosis treatment as presented in Fig. 3. To encourage the uptake of the intervention, study team personnel conducted 876 phone calls (warm handoffs) to the participants who provided phone numbers. A total of 544 of these calls were answered for a contact rate of 62.1%. Out of the 862 calls attempted by the IVR system, there were 400 successful calls, for a contact rate of 46.4%.

The proportion of women who accessed the intervention website within 60 days after the initial email contact was significantly

Table 2
Seven osteoporosis treatment barriers identified and ranked by survey respondents.

Barrier	Ranked#1	Ranked#2	Ranked#3	Cumulative ^a
Osteonecrosis of the jaw concerns	128	59	135	322 ^b
Gastrointestinal problems	109	46	136	291 ^b
Atypical fracture concerns	101	48	131	280
Preference for natural supplements	120	32	115	277
Drug inefficacy concerns	73	51	142	266 ^b
Medication interaction concerns	67	23	142	232 ^b
Difficulty remembering medication	29	11	139	179

^a Cumulative represents the total number of persons who ranked each of the barriers as #1, #2 or #3.
^b Endorsed by all participants who ranked 4 or more barriers equally.

greater (46.2%; 296 out of 641) among the participants who provided an email address compared to those who did not provide an email address, (11.6%; 81 out of 701) ($p < 0.0001$) (Fig. 4). Compared to the women who did not logon to view the intervention materials within the 60 day period, women who logged on to their personalized website were more likely to have provided an email address (aOR = 6.07, 95% CI 4.53–8.14), and less likely to self-report depression (aOR 0.72, 95% CI 0.51–0.996) (Table 3). In addition, there was an 18% lower odds of accessing the videos for every ten years of advancing age (aOR = 0.82, 95% CI 0.66–0.95). Individuals who interacted with the warm handoff or the IVR component of the intervention were less likely to logon to the intervention website compared to those who were not exposed to the warm handoff or

IVR components of the intervention.

4. Discussion

We designed a multi-modal intervention for women at high risk of fracture tailored to barriers or concerns about osteoporosis treatment, readiness to behavior change, osteoporosis treatment history, and race/ethnicity. This intervention employed print and audiovisual components, and was delivered via internet and mail. We further encouraged interaction with our material by delivering DVDs, personalized reminder phone calls, and IVR calls. Approximately a quarter of women interacted with their personalized website, and among those who provided email addresses, 46.2%

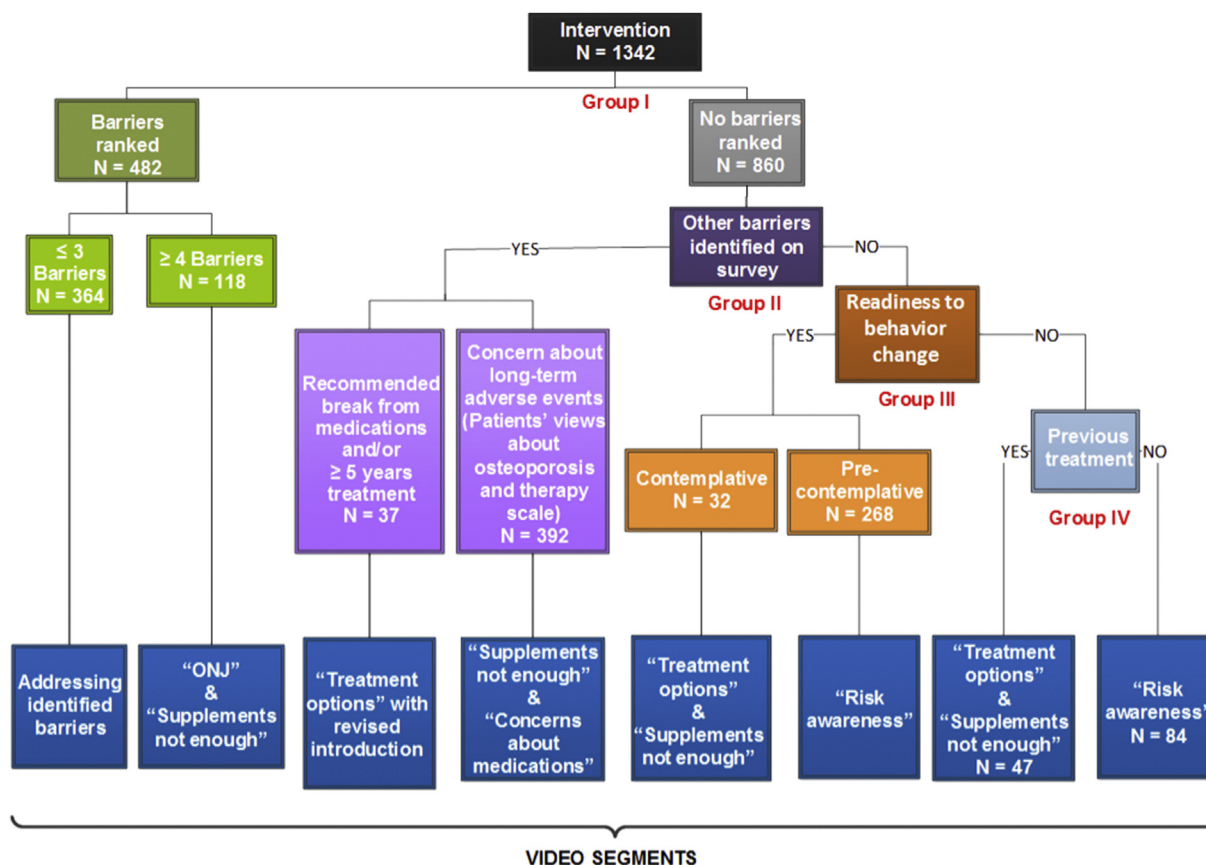


Fig. 3. Tailoring of video segments for women in the intervention arm of the Activating Patients at Risk for Osteoporosis (APROPOS) Study. Individuals were assigned video segments based on four mutually exclusive, hierarchical levels: *Group I*: Ranked barriers to osteoporosis treatment, *Group II*: Other barriers identified on the survey including a physician recommended break from medications and/or ≥ 5 years treatment, or concerns about long term adverse effects as identified on the Patients' Views about Osteoporosis (osteo) and therapy scale, *Group III*: Readiness to behavior change based on the Weinstein Precaution Adoption Process Model (PAPM), or *Group IV*: Previous treatment history. ONJ, osteonecrosis of the jaw.

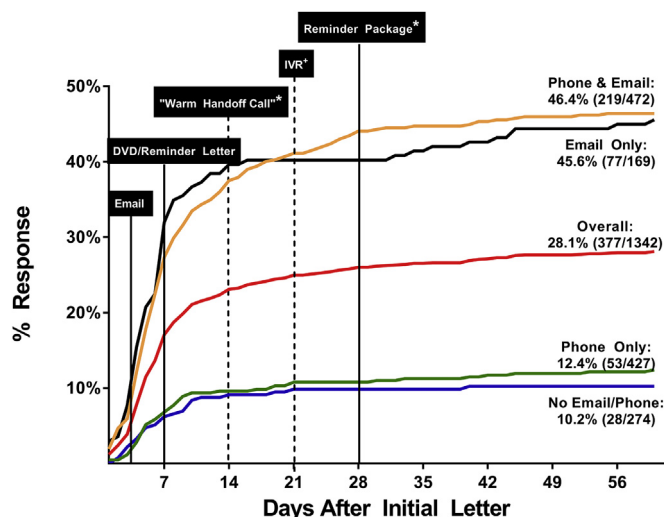


Fig. 4. Proportion of participants interacting with the video program online by contact information. Phone only, email only, phone & email indicate phone number, email, or both provided on baseline survey, respectively. No email or phone indicates no email or phone number was provided on the baseline survey. Warm handoff call informed participant of reason for intervention materials, as well as attempted to identify and address barriers to watching videos. Reminder package contained copy of introductory letter detailing instructions on how to access video program online and another DVD with individualized video intervention. * Timing of these materials varied up to ~1week. +Varied based on when/if warm handoff call completed. IVR, interactive voice-response [5].

reviewed the materials online. The relatively large proportion of women interacting with the intervention online is notable given the older age of the U.S. women involved in this study. This may reflect the increasing proportion of older adults who use the

internet as a source for health-related information [50]. To our knowledge, this is the first behavioral, theory-informed, patient-tailored, multi-modal intervention aimed at increasing initiation of osteoporosis therapy in a high fracture risk population.

Attention to bone health through initiation of osteoporosis treatment after a fracture remains a significant challenge despite the availability of national clinical guidelines and quality measures [51,52]. A recent systematic review of interventions designed to improve osteoporosis medication initiation in patients with osteoporosis highlights that multifaceted interventions targeting high-risk patients and their primary care providers through patient educational material, physician notification, and/or physician education may improve the management of osteoporosis [53]. Further, an associated meta-analysis pooling the results of six trials showed a 20% absolute increased incidence of osteoporosis treatment initiation and a 40% increase in either bone mineral density testing and/or osteoporosis treatment initiation in high-risk patients following interventions aimed at patients and/or physicians [53]. Community pharmacist-based interventions for primary non-adherence to osteoporosis medications have shown some success in the Netherlands, but there is no similar intervention program or strategy in the US [54,55]. There exists an urgent need to develop effective strategies to promote adoption of appropriate osteoporosis treatment at the patient level and, therefore, we developed a novel, tailored intervention in older women with prior fractures, the population most at risk for subsequent fractures, and tested it in a randomized controlled trial.

Tailored, interactive educational programs hold promise in healthy life-style promotion (e.g., smoking cessation [56], nutrition education [57], physical activity [58] etc.) and self-management in chronic disease (e.g., diabetes mellitus [59], cancer [60]). Tailoring can increase the perceived relevance of a message by stimulating attention, comprehension, self-referential thinking and the depth

Table 3

Adjusted (aOR) and unadjusted odds ratio (OR) (and 95% confidence intervals) estimates of logging on the website within 60 days of intervention initiation.

Characteristic	Category	Number (%)	Crude		Adjusted ^b		Adjusted ^c	
			OR	95% CI	OR	95% CI	OR	95% CI
Email	No	81 (21.5%)	ref					
	Yes	296 (78.5%)	6.57	(4.97, 8.68)	5.10	(3.56, 7.31)	6.07	(4.53, 8.14)
Phone	No	105 (27.8%)	ref					
	Yes	272 (72.2%)	1.40	(1.08, 1.81)	1.23	(0.86, 1.75)	0.82	(0.66, 0.95)
Age, every 10y			0.66	(0.54, 0.74)	0.74	(0.60, 0.94)		
Race/ethnicity	Not Caucasian	14 (3.7%)	ref					
	Caucasian	363 (96.3%)	2.38	(1.33, 4.24)	1.67	(0.72, 3.85)	1.76	(0.95, 3.27)
Education	Less than high school	3 (0.8%)	ref					
	High school	41 (11.0%)	2.36	(0.70, 8.03)	1.17	(0.22, 6.30)		
	Some college or more	329 (88.2%)	5.79	(1.77, 18.91)	1.80	(0.35, 9.28)		
Recruitment site	Worcester, MA	63 (16.7%)	ref					
	Birmingham, AL	44 (11.7%)	0.82	(0.53, 1.28)	0.71	(0.39, 1.32)		
	Cincinnati, OH	35 (9.3%)	0.97	(0.60, 1.55)	0.79	(0.43, 1.45)		
	Los Angeles, CA	46 (12.2%)	1.77	(1.11, 2.80)	1.47	(0.81, 2.65)		
	New York, NY	52 (13.8%)	1.37	(0.89, 2.12)	1.37	(0.78, 2.41)		
	Pittsburgh, PA	55 (14.6%)	1.18	(0.78, 1.80)	0.87	(0.49, 1.54)		
Concerned about osteoporosis	Seattle, WA	82 (21.8%)	1.49	(1.01, 2.20)	1.17	(0.71, 1.95)		
	No	133 (38.2%)	ref					
Depression	Yes	215 (61.8%)	1.21	(0.93, 1.56)	1.15	(0.82, 1.61)		
	No	70 (19.4%)	ref					
Prior osteoporosis drug use	Yes	290 (80.6%)	0.86	(0.64, 1.16)	0.66	(0.45, 0.98)	0.72	(0.51, 0.996)
	No	264 (71.5%)	ref					
Readiness to behavior change ^a	Yes	105 (28.5%)	1.54	(1.18, 2.00)	0.79	(0.55, 1.12)		
	Precontemplative	239 (74.2%)	ref					
Health literacy	Contemplative	83 (25.8%)	1.06	(0.79, 1.43)	0.96	(0.64, 1.44)		
	Inadequate	22 (5.9%)	ref					
	Adequate	350 (94.1%)	2.85	(1.79, 4.54)	1.58	(0.79, 3.18)		

^a Readiness to behavior change assessed using a modified form of the Weinstein Precaution Adoption Process Model (PAPM).

^b Adjusted for all characteristics.

^c Adjusted for age, email, race/ethnicity, depression.

of message processing [61]. We tailored the health messages in our study to race/ethnicity and the individual characteristics related to health behavior with hopes of increasing the probability for materials to be considered [62]. Homophily (i.e. identification with the storyteller) is a mechanism for social influence in online health information communication [63]. Individuals are more likely to adopt the advice offered through educational messages, such as ours, when they perceive more homophily with the information stimulus [63]. In a controlled experimental study on the spread of a health innovation through fixed social networks, in which homophily was independently varied, homophily increased overall adoption of a new health behavior, especially among those most in need of it [64].

Efforts to promote initiation of osteoporosis medication need to expand outside the infrequent face-to-face clinical encounters focused on bone health. The internet represents an alternative venue where online educational materials are convenient, easily accessible, under the learners' control, and overcome time and mobility constraints, have the ability to reach a large number of people and are less costly, scalable and reusable [36,65]. Our educational intervention promoting osteoporosis therapy and utilizing risk communication principles [66–68] was implemented via the internet. In addition to asynchronous learning depending on the participants' schedule, those who engaged with materials in the online environment could review the educational content as many times as they deemed necessary. Because an estimated 59% of adults aged 65 and older use the internet [69], online interventions may reach a substantial proportion of the geriatric population at risk for future fracture, as evidenced by our findings. In one study, older adult exposure to an 8-week theory-based program entitled Bone Power that included learning modules, discussion boards, and other resources resulted in greater improvement in osteoporosis knowledge, self-efficacy/outcome expectations for calcium intake and exercise behaviors compared to the group of adults who were not exposed [70]. In our past experience, a direct-to-patient, internet-based educational video intervention produced a trend toward greater use of osteoporosis medication among patients taking chronic glucocorticoids when the patients self-initiated an educational video on osteoporosis prevention [71]. This suggests that in order to change behavior and ultimately increase osteoporosis medication use, patients need to actively engage with educational interventions.

The delivery strategy of health messages influences the effectiveness of health educational programs. Compared with written messages, audiovisual messages, consonant with our approach, increase recall of information in older adults [72]. Video-based educational materials employing storytelling by patient actors such as those in our study are engaging and influential in promoting behavioral interventions [73–75]. Narrative communication is the basic mode of human interaction and audiences may view messages as more personal, realistic, believable, and memorable compared to didactic forms of communications [46]. Storytelling promoted social support, decreased participants' sense of isolation, relieved stress, boosted self-confidence and motivated behavior change in African Americans with diabetes [76]. A narrative video on use of mammography and cancer-related beliefs in African American women was better liked, enhanced recall, reduced counter-arguing, increased breast cancer discussions with family members, and was perceived as more novel than an informational video [75]. Despite the positive effects of storytelling on promotion of behavior change in some populations [75,76], our team's previous experience using a narrative communication intervention did not increase appropriate BMD testing and

osteoporosis treatment in the targeted population beyond a simpler intervention allowing self-scheduling, thus indicating the need for further testing of this approach in osteoporosis [24].

We utilized reminder messages through phone calls and IVR in an effort to increase participant engagement with the video intervention. An IVR call and follow-up letter highlighting the benefits and risks of bisphosphonates increased two-fold the initiation of bisphosphonate therapy in older women with osteoporosis receiving care in a managed care setting [77]. However, we found that despite a ~40–60% success rate in reaching the participants through IVR and phone calls, which occurred when participants did not log on to the intervention website, these reminders did not have an incremental benefit in influencing the participants to access their personalized videos online. In fact, those participants who were contacted through warm handoff and IVR were significantly less likely to interact with their web educational program. A possible explanation could be that the individuals we reached by phone and who were effectively exposed to warm handoff and IVR, were systematically different than those who logged on early or who we could not successfully contact by phone. Alternatively, the participants who were contacted via the warm handoff procedure by the study personnel may have decided that they did not need or want the osteoporosis education provided on their personalized website and chose not to log on online to view the intervention materials.

Our intervention design has some limitations. We strived to design a highly tailored intervention responsive to individual barriers to osteoporosis treatment that also accounted for an individual's readiness to behavior change. However, not all barriers were considered modifiable, some participants failed to list treatment barriers, and others ranked several barriers as equally important. We did not incorporate a conjoint analysis or alternative approach to extricate participants' specific reasoning and rankings. Thus, we had difficulty providing an intervention individually tailored on each and every component of participant-provided data as envisioned, which may impact the overall effectiveness of our intervention. Further, it remains unclear what the most important elements are for optimal tailoring. For example, while for some individuals tailoring on race/ethnicity may be important, for others it may be less critical. Finally, the choice of the behavioral model governing our intervention development may be questioned. There are many behavioral theories addressing behavior change and evidence implementation; we chose to model our intervention development on the IMB model, which has been extensively used in studies of HIV medication adherence [32].

In summary, we developed and successfully implemented a tailored, multi-modal patient-directed intervention promoting initiation or re-initiation of osteoporosis medications in women at high risk of future fracture. Women who provided an email address were considerably more likely to interact with our intervention online. If our educational intervention proves effective at increasing osteoporosis treatment rates, similar web-based interventions aimed at individuals who obtain their health information online have the potential to address osteoporosis treatment barriers and our novel approach may be applicable to other chronic diseases.

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Appendix A

Barriers identified

1. Being raised in a family where we were wary and fearful of any kind of medications
2. Being told by my dentist that I could get bone and jaw cancer after taking the medication for a few years.
3. By making significant lifestyle changes to be more healthy (e.g., combining the right kind of food, activity, reducing stress, and other behaviors), it should not be necessary to take the medication.
4. Experiencing GI problems when I take oral medications
5. Hating the thought of taking any and all medications
6. Having a mother and grandmother who took similar medicines without any benefit
7. Having concerns about the side effects after reading studies and other information that I found.
8. Having had previous negative reactions when taking other drugs.
9. Having to pay a lot for this type of medication
10. Having to remember to take medication.
11. Hearing that these medications can also make your bones brittle
12. Liking to try natural remedies first
13. Not believing that my doctor is acting in my best interest
14. Not having insurance coverage for this type of medication since it is considered preventative not life-threatening
15. Not knowing how these medications would interact with other medications
16. Not knowing if my doctor really knows what is right for me
17. Not knowing what the long term effect might be of a drug that can actually change your bone
18. Not thinking that there have been enough studies done to really know about the side effects of these medications especially when someone has other medical conditions (e.g. for diabetes)
19. Taking medication could cause me to have more frequent doctor visits
20. Taking these medicines is complex and inconvenient
21. Trying to get more calcium from food to avoid taking medications (note: dietary supplement)
22. Wondering whether there will be something better that will come along if I wait
23. Worrying about the cumulative/long-term side effects of these drugs because of their toxicity.
24. Worrying about the possible side effects of this medication
25. Worrying how the medication will affect my digestive system–based on other meds that I have taken.

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