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The PAADRN Study: A design for a randomized controlled practical clinical trial to improve bone health

Stephanie W. Edmonds, RN, MPH¹, Fredric D. Wolinsky, PhD^{1,2}, Alan J. Christensen, PhD^{1,3}, Xin Lu, MS¹, Michael P. Jones, PhD⁴, Douglas W. Roblin, PhD⁵, Kenneth G. Saag, MD, MSc⁶, and Peter Cram, MD, MBA^{1,7} on Behalf of the PAADRN Investigators*

¹Division of General Medicine, University of Iowa Carver College of Medicine, 200 Hawkins Dr., Iowa City, IA 52242

²Department of Health Management and Policy, University of Iowa College of Public Health, 105 River St., Iowa City, IA 52242

³Department of Psychology, University of Iowa, E11 Seashore Hall, Iowa City, IA 52242

⁴Department of Biostatistics, University of Iowa College of Public Health, 105 River St., Iowa City, IA 52242

⁵Kaiser Permanente of Atlanta, 3495 Piedmont Rd. NE, Atlanta, GA 30305

⁶Department of Rheumatology, University of Alabama at Birmingham, 1530 3rd Ave. S, Birmingham, AL 35294

⁷Center for Comprehensive Access and Delivery Research and Evaluation, 601 Highway 6 West, Iowa City Veterans Administration Medical Center, Iowa City, IA

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1. Introduction

An estimated 55% of Americans 50 years and older will be diagnosed with osteoporosis or low bone density, and this prevalence is expected to increase substantially as the population ages [1]. The most serious consequence of osteoporosis is hip fracture, a major cause of morbidity and mortality among the elderly [2]. Fortunately, Dual Energy X-Ray Absorptiometry (DXA) provides low-cost screening, making it possible to diagnosis osteoporosis and initiate treatment before fracture occurs [2, 3]. Unfortunately, patients at risk for fractures are not always aware of their risk and thus do not recognize the need to take action to reduce this risk [4–17].

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Corresponding author: Stephanie W. Edmonds RN, MPH, University of Iowa, Department of Internal Medicine – C44-L GH, 200 Hawkins Dr., Iowa City, IA 52242, Stephanie-edmonds@uiowa.edu, (319) 356-1761 Fax: (319) 356-1229.

*Jeffrey R. Curtis, MD, MPH, Sarah L. Morgan, RD, MD, CCD, FACP, Ryan Outman, MS, Brandi E. Robinson, MPH, Janet A. Schlechte, MD, Samantha L. Solimeo, PhD, Jessica H. Williams, MPH, PhD, Nicole C. Wright, MPH, PhD, David J. Zelman, MD

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Deficiencies in the processes and procedures for communicating and following up on completed DXAs between DXA testing centers, providers, and patients play an important role in suboptimal patient care. Problems in virtually all aspects of the test result reporting and communication process have been documented and result in important test results being overlooked or missed [18–23]. We have shown that 23% of DXA reports appeared not to have been reviewed by a provider [4]. Others found that 20% of study participants said they were not informed of their DXA results [9] and almost half of women with documented low bone mineral density (BMD) reported having normal BMD [8]. Poor communication of DXA results is problematic because the costs of testing are still present while the benefit of treatment and prevention of fractures is not.

Given the suboptimal communication of DXA results, a number of trials in recent years have tested interventions designed to spur patients and providers to take action after DXA. These studies have demonstrated increases in BMD testing, osteoporosis treatment, and prescription fill rates [24–28]. Few published studies, however, have examined the impact of targeting patients (i.e., *patient activation*) to improve bone health. Patient activation is defined as “enhancement of patient involvement in personal health care through teaching of self-care skills and principles of prevention” [29]. A limited number of patient activation intervention studies in osteoporosis have demonstrated that mailing patients their DXA results may lead to improved recall of test results among those with low bone density [30, 31], an increase in calcium use [17], physical activity initiation, and an increase in hip BMD [32]. In a pilot study, we examined the impact of mailing patients their DXA results and found an 8% increase in use of antiresorptive therapy in patients that received a DXA result mailing compared to those that received usual care, though these differences were not statistically significant [33, 34].

We set out to design a low-cost, highly generalizable intervention and to test this intervention in several diverse clinical settings using the framework for practical clinical trials (PCTs) [35]. The Patient Activation After DXA Result Notification (PAADRN) Study aims to evaluate the effects mailing a letter with a patient’s DXA result and a bone-health educational brochure will have on patient activation. We hypothesize that the intervention will increase pharmacotherapy and calcium/vitamin D use in those with osteoporosis while decreasing overuse in those with normal or low BMD (i.e., guideline concordant care). We also expect that the intervention will increase patient satisfaction with their bone-related healthcare, and increase osteoporosis-specific knowledge and self-efficacy as compared to patients that do not receive their mailed DXA results. Figure 1 summarizes our conceptual approach, and Table 1 summarizes our aims, endpoints, and hypotheses. (Figure 1) (Table 1). In this article, we present the protocol for the PAADRN Study.

2. Methods

2.1. Design and Setting

PAADRN is a multicenter, randomized controlled trial. Patients are being recruited at three diverse clinical sites: the University of Iowa (UI), Kaiser Permanente of Georgia (KP) and the University of Alabama at Birmingham (UAB). Patient recruitment began in February 2012 and data collection will be completed in July 2015. The three sites were chosen because of their diversity in academic affiliation, geographic location, and patient populations served (Table 2). We anticipate enrolling 7,500 patients overall. Prior to study enrollment, PIs at each site sent a brief email to providers within their health system notifying them of the PAADRN study. The email provided a general overview of the study and an email address for questions and concerns; of note, less than 10 providers in-total responded to the email with questions. The PAADRN research protocol was reviewed and approved by the Institutional Review Boards at each site.

2.2. Participant Eligibility Criteria and Recruitment

As a practical clinical trial, PAADRN was designed to maximize generalizability and enroll a diverse population of patients using minimal exclusion criteria. We are enrolling all men and women 50 years old and older who present for DXA (as ordered by their health care provider) at any of the three study sites. Exclusion criteria are limited to: 1) the inability to read or speak English (as many study instruments have not been validated in non-English speakers); 2) prisoners; and 3) patients with significant mental, visual or hearing impairments (because their impairments would make it difficult to complete the study interviews and/or obtain informed consent). Research assistants (RAs) use their best-judgment in order to screen for mental, visual, or hearing impairments.

Eligible participants are being identified at each site through review of the computerized DXA unit appointment schedules. Patients are being recruited using several processes to accommodate the varying work flows at each study site. RAs contact patients using a combination of mailed recruitment letters and/or phone calls up to 28-days before their scheduled DXA visit. Either written or verbal informed consent is obtained depending on IRB guidelines at each site. Participating patients are provided financial compensation for their time (e.g., a \$20 gift card, parking voucher, etc. depending on policies at each site).

2.3. Baseline Data Collection

Baseline data are being collected between 28 calendar-days prior to and 3 business-days following each participant's DXA to balance recruitment goals with the need to avoid undue delay in completing baseline data collection. One concern for allowing interviews after patients undergo their DXA is that their self-reports may have been contaminated by a conversation with their health care provider. In order to analyze for potential contamination bias, RAs ask patients two questions at the completion of all baseline interviews occurring after the DXA scan: 1) "Since your DXA, have you talked to a health care provider about your DXA results?"; and, 2) "Since your DXA have you seen a copy of your DXA results?" RAs at all sites are conducting the baseline interviews using computer-assisted interviewing software package operating from a secure web-based data collection platform (REDCap [36]). Because randomization does not occur until five days later, the RAs are blinded when conducting the baseline interviews. Baseline data elements and measures are listed in Table 3.

RAs at each site undergo standardized training using an interviewer's manual prepared by the PAADRN Study Coordinator (SE). The manual covers an array of topics including definitions and pronunciations of medical terms, discussion of difficult survey questions, as well as more general interview training issues. All RAs are required to complete the training program and observe several interviews conducted by experienced RAs. All RAs "role play" at least two interviews with an experienced interviewer. Successful completion of this training module is required before the RA can interview patients. Ongoing quality control is conducted by experienced study coordinators at each site who periodically observe and audit each RA's performance on a random basis to assess for departures from the study protocol and standard interviewing techniques (e.g., leading study participants in answering questions).

2.4. Randomization

Randomization takes place approximately five days after completion of the DXA and the baseline interview and is performed at two levels within each site. In the first level, doctors are randomized to treatment groups A (intervention), B (usual care) and C (mixture of A and B) as shown in Figure 2. Group A and B are standard for a RCT but Group C is a unique approach to examine contamination effects. Since Group C providers have patients assigned

to both intervention and usual care arms, we can examine “physician spill-over” effects (i.e. diffusion, or the extent to which the intervention affects physician behavior towards the patients receiving usual care). Intervention derives from patient activation (mailed DXA results described below). Usual care differs somewhat at each study site, as shown in Table 2. Since patient DXA referral volume is a potential confounder of treatment effect on outcome and referral volume cannot be randomized, site-specific lists of doctors referring at least three patients for DXA scans in 2010 and 2011 were created. Each list was sorted into decreasing order of the number of DXA scan referrals made during 2010–2011. Permuted-block randomization was used within each site so that each sequential block of three doctors were randomly assigned to the three treatment groups. This phase of pre-study randomization covers those doctors expected to order the vast majority of DXA scans. Doctors with low or even no past referrals, including new hires, may or may not contribute patients to this study. These doctors will be randomized to groups A, B and C at the time their first patients enter the study, as described below.

In the second level, patients are assigned to the same treatment group as their doctors. However, patients of group-C doctors are reassigned to either treatment group A or B in blocks of size 2 as follows. If this patient is a group-C doctor's first, third, ... referred patient, then a virtual fair coin is flipped to determine reassignment to A or B. If this patient is the second, fourth, ... referred patient of this same doctor, then this patient receives the opposite assignment as the previous patient with the same doctor. The doctors remain in group C.

For doctors who have referred fewer than three patients for DXA scans in 2011 or who are new hires, a computerized balls-in-a-box strategy is used. Initially, each site-specific box has 3 A balls, 3 B balls and 3 C balls. A new patient arrives for randomization. If his/her doctor has no patients already in the study, then a ball is chosen at random from the box, which defines the treatment assignment for both patient and doctor. The ball is not returned to the box. If the box ever becomes empty, it is refilled to the initial conditions of (3,3,3). If the new patient's doctor has a patient already assigned through the balls-in-a-box scheme, then the new patient is assigned to the same treatment group as his/her doctor, but if Group C, then reassigned to either A or B, as already described. At this point a ball corresponding to this type is removed from the box. If no balls of this type are in the box, then the number of balls of the other two types is each incremented by one. Note that the box contents change after each assignment of a new patient rather than assignment of a doctor new to the study, which stems from our priority of balancing the number of patients across treatment groups.

2.5. Intervention

The PAADRN intervention consists of a 1) customized letter, plus 2) a bone-health educational brochure (described below) developed specifically for this study. These materials are mailed to each intervention patient four-weeks after the completion of their DXA. All letters are mailed from the UI coordinating center.

2.5.1. Usual Care—All patients in our study will receive usual care. Those that do not receive the letter and brochure mailing will serve as the control group. In usual care, clinicians will disseminate DXA results and treatment information as they normally would (by means of telephone, office visit, email, or not at all). Table 1 briefly describes usual care after DXA at each of the three study sites.

2.5.2. Letter—In the months leading up to enrollment, we developed and pilot tested a letter for conveying DXA results to patients based upon the prior research of our team and others. This one-page letter is written at a sixth grade reading level [37] and is customized to incorporate each patient's DXA results and absolute fracture risk. The letter provides each

patient with his/her DXA result (T-score) and diagnosis (normal, low bone density, or osteoporosis). In addition, the letter contains each patient's 10-year probability of a major osteoporotic fracture reported numerically as both a percentage and fraction, and visually as a bar-type graph. Fracture risk is calculated using the FRAX online calculator (www.shef.ac.uk/FRAX/) [38]. The bar-graph displays a patient's fracture risk in terms of a percent and using a universally recognized stoplight color system which 0–9% is low risk (green), 10–19% is moderate risk (yellow), or 20% is high risk (red). Otherwise each letter is identical and instructs patients on steps that can be taken to enhance their bone health (Figure 3). Details about the letter and brochure development will be available elsewhere [39, 40].

2.5.3. Brochure—The educational brochure that accompanies the result letter (Figure 4) was developed with the input of clinicians, health communication experts and graphic artists. It was also written at a sixth-grade reading level. The brochures underwent an extensive pilot testing and revision process. The brochure describes five steps that patients should take to improve their bone health: 1) Talk to your health care provider; 2) Calcium/Vitamin D optimization from dietary sources and/ or supplements and medications; 3) Activity and fall prevention; 4) Tobacco cessation; and, 5) Alcohol reduction. The brochure also contains information on osteoporosis and DXA.

2.6. Follow-up Data Collection

Each patient will be re-interviewed by telephone at approximately 12- and 52-weeks after their DXA for follow-up data collection to assess key outcomes as described below. The interviews are being conducted by trained interviewers at the UI Social Science Research Institute using computer-assisted telephone interview software (WinCATI 4.2, Sawtooth Technologies, Inc. Northbrook, IL).

2.7. Study Outcomes and Statistical Analyses

PAADRN focuses on seven main outcomes: 1) guideline concordant pharmacotherapy and non-pharmacotherapy (i.e. Calcium/Vitamin D use); 2) patient knowledge of their DXA results 3) osteoporosis specific knowledge; 4) health related quality of life (HRQoL); 5) satisfaction with bone-related health care; 6) osteoporosis-specific self-efficacy; and 7) patient activation. We have one “treatment outcome” and six “patient-centered” outcomes as described below:

Treatment outcome

- Guideline concordant use of pharmacologic and non-pharmacologic therapy (including treatment maintenance, initiation, supplementation, or discontinuation) using patient self-reports supplemented with pharmacy claims records from UI and KP and medical record review from a random sub-set of patients. Appropriate use will be decided using guidelines from the National Osteoporosis Foundation (NOF) and agreed upon by study clinicians that specialize in the care and treatment of osteoporotic patients. Current NOF guidelines for women and men 50 years and older are to consider pharmacotherapy for patients who:
 - Had a hip or vertebral fracture
 - Have a T-score ≤ -2.5 at the femoral neck or spine.
 - Have a T-score between -1.0 and -2.5 at the femoral neck or spine and a FRAX® of $\geq 20\%$ [41].

Patient-centered outcomes

- Patients' understanding of their DXA results (i.e. normal, low BMD, or osteoporosis) and validating patient self-reports with the DXA result report.
- Differences in osteoporosis-specific knowledge using the 'Osteoporosis and You' scale [42].
- Changes in health-related quality of life using the Euroqol EQ-5D-3L [43, 44].
- Differences in bone health-specific health care satisfaction using a newly developed bone health-specific health care satisfaction scale comprised of 5 Likert scaled items.
- Changes in self-efficacy in bone-related health behaviors using the Osteoporosis Self-Efficacy Scale [45].
- Differences in patient activation in their health using 6-items from the Patient Activation Measure (PAM) [46].

2.8.1. Statistical Power

Estimating statistical power for the multiple outcomes of interest while accounting for the clustering of the data within sites and physicians and patient attrition is challenging. Sample size estimates were primarily based upon evaluating guideline concordant pharmacotherapy use among patients between the intervention arm and the control arm. To estimate power, we calculated the effective sample size, which is generally smaller than the actual sample size due to the effect of clustering within sites and providers. The sample size is effectively reduced depending on the number of patients per physician (providers per site) and the intra-provider (intra-site) correlation (ICC) as follows:

$$\text{Effective sample size} = \text{Actual sample size} / [1 + \text{ICC} * (\text{Cluster Size} - 1)]$$

We assumed an ICC of 0.05 and 3 patients per provider on average (i.e., roughly 1 patient with osteoporosis per provider). In order to detect change in guideline concordant therapy we have calculated power for patients with osteoporosis to be treated with pharmacotherapy and calculated power for those with normal or low bone density to not get pharmacotherapy. Assuming the recruitment of 7,500 patients, of whom 1,500 (20%) have a diagnosis of osteoporosis, we will have 88% power to detect an 8% increase in guideline concordant pharmacotherapy in the intervention arm as compared to the control arm (e.g., 50% of patients with osteoporosis receiving treatment in the control arm versus 58% in the intervention arm). We derived an estimate of 20% of patients with osteoporosis from internal data collection at all three sites and saw an 8% increase in the use of antiresorptive therapy from 54% to 62% in the intervention group from our pilot [34]. Additionally, we will have 83% power to detect a 4% reduction in pharmacotherapy overuse in patients with normal bone density or those with low bone density that should not receive pharmacotherapy based on NOF guidelines. These two power calculations are conservative because they focus on key sub-groups of study patients (i.e., those with osteoporosis, those who should not receive pharmacotherapy); if, instead, we were to evaluate a composite outcome of "guideline concordant therapy" (yes/no) among all study patients statistical power would be even better. For patient-centered outcomes sample size estimates were based upon prior studies suggesting that a change of 0.5 standard deviations is an appropriate benchmark for most instruments [47]. Accordingly, we will have 99% power to detect a 0.9 point increase in osteoporosis-related knowledge, and 99% power to detect a 19.6 point increase in osteoporosis self-efficacy [41]. Note that power was somewhat reduced from our original estimates; this was the unfortunate consequence of budgetary reductions and resulting reductions in resources for patient recruitment.

2.8.2. Statistical Analysis

Our primary analyses will compare each outcome between patients randomized to the patient activation intervention versus usual care. Most outcomes will be assessed by evaluating changes (e.g., osteoporosis-specific knowledge) between baseline and follow-up (a difference in differences approach). We will use standard bivariable methods (t-test, chi-square test, ANOVA) to compare pharmacotherapy or Calcium/Vitamin D use or patient satisfaction among all usual care patients as compared to all intervention patients. We will examine the potentially differing impact of the intervention at 12-weeks and 52-weeks using both a single model interaction between the intervention indicator and the 12 vs. 52 week follow-up indicator and separate models that evaluate the impact of the intervention at each time point. We will report effects occurring at 12 week as “immediate effect” and effects at 52 weeks as “enduring effects.”

We will then conduct similar stratified analyses among key pre-defined subgroups based on: 1) DXA result (normal, low, or osteoporosis); 2) study site; 3) patient age, race, and gender; and, 4) provider DXA volume; and 5) patients undergoing a first DXA versus patients undergoing a repeat DXA. We will use multivariable models to examine study outcomes (e.g., HRQoL) while adjusting for differences among intervention and control group patients and accounting for clustering of patients within study sites and providers. We will examine the potential for diffusion effects by comparing outcomes among usual care patients among Group 2 and Group 3 providers. All analyses will be conducted using SAS (SAS institute, Cary, NC) and SPSS (IBM, Armonk, NY).

We are aware that multiple outcomes will increase the chances of a Type 1 error (i.e., finding an effect when one truly does not exist). We will examine the impact of our study using both adjusted and unadjusted P-values. More specifically adjusted analyses will use Bonferroni adjustment to account for multiple comparisons. Additionally, our trial is a complex behavioral intervention and, unlike a study of a medication or medical device, judging the success of our study based upon a single outcome such as mortality or health-related-quality-of-life is unlikely to fully capture the impact of our intervention. We are intentionally evaluating our intervention using a diverse spectrum of outcomes designed to fully capture the potential impact of our intervention. We believe that journal editors and readers will be able to weigh the various outcomes individually and in aggregate to make their own decisions about whether our intervention “works.”

We will initially evaluate the cost-effectiveness of the intervention using a societal perspective by calculating the incremental cost per quality adjusted life year (QALY) of the intervention compared to usual care over the 52-week study period. We will then extend our analyses to encompass a longer-term (patient lifetime) perspective using an existing cost-effectiveness model[48]. As with most traditional cost-effectiveness models, this model requires three different types of data; 1) cost; 2) effectiveness; and 3) utility. Cost data derived from the interventional trial will include costs related to the activation intervention itself (e.g. postage, printing) and costs related to the healthcare required by intervention and control patients (e.g. medications, office visits). The effectiveness of the intervention will primarily be captured through increases in use appropriate pharmacotherapy (osteoporosis patients only), reductions in use of inappropriate pharmacotherapy (patients with normal and low BMD), increases in use of Calcium/Vitamin D (all patients), and changes in utility. Utility values will be obtained by converting EQ-5D scores obtained at baseline and follow-up into health state utility values using standard methods.

3. Discussion

We are conducting a practical clinical trial (The PAADRN Study) to examine the impact of mailing patients their DXA results and an educational brochure on subsequent bone-related health behaviors and other patient-centered outcomes. We hypothesize that the intervention will increase osteoporosis-specific patient knowledge, satisfaction with bone-related care, and self-efficacy, and improve bone-related health behaviors and treatments.

A number of observations related to our trial warrant brief mention. First, by design there is marked heterogeneity across our study sites. For example, UAB has an existing and highly developed osteoporosis clinic; UI serves a highly educated rural population with few underrepresented minorities; and KP primarily serves patients enrolled in their own managed care insurance plan. This heterogeneity is both a strength of and challenge to our study.

Second, our intervention consists of mailing information to patients. Since the original development of this grant, the differences in usual care at each of the three sites have become greater as care has evolved. As Table 2 demonstrates, KP is now routinely mailing DXA results to patients (albeit in fairly undeveloped format) and UI has a patient web portal which allows patients to see their DXA results via the internet (albeit in a format that is not easy for patients to understand). These changes at KP and UI reflect modest progress towards sharing test results with patients. However, many of these systems have given little thought to health literacy, numeracy or the educational level of the patient [49, 50]. The intervention used in this study was developed with health literacy and numeracy in mind, was evaluated by our target audience and provides immediate information on how patients can improve their bones. Also, as new technologies become more widely disseminated, it is reasonable to question whether other modes of communicating DXA results to patients (e.g., internet portals, email, or text-messaging) might have a different effect on study outcome. While these new technologies are important avenues for future research, they cannot be added to our study at this time given both its current complexity and practical nature.

Third, the clinical treatment of patients with reduced bone density continues to evolve [51]. There are many unanswered clinical questions such as when to initiate medical therapy for patients with low bone density, when to discontinue pharmacotherapy, and the difference in treatment practices across provider specialties [6, 9]. Finally, it would be important to study our intervention (mailing patients their DXA results) in the broader context of other test results that are ordered in modern medical practice. That is, would patients and providers accept “pushing” multiple test results directly to patients (e.g., blood pressure, hemoglobin A1C levels for diabetes, sexually transmitted diseases) and how would these impact patient-centered outcomes?

In conclusion, with funding from NIA we are conducting a practical clinical trial (the PAADRN Study) to investigate the impact of the direct mailing of DXA results and educational information on patient-centered bone-health outcomes. The results from this trial will advance our understanding of how best to communicate DXA results to patients and should help to inform how best to communicate the results of other types of tests to patients.

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Fig. 1.
Conceptual Model

Fig. 2.
Randomization flowchart

Fig. 3.
Sample DXA result letter

What Can I Do for My Bone Health?

Steps for Strong & Healthy Bones

Front Cover

PAADRN

For more information:

Talk to your health care provider.
Remember to bring this brochure
and your letter to your appointment.

You can visit these websites too.

National Institutes of Health
www.bone.nih.gov
800-624-BONE

National Osteoporosis Foundation
www.nof.org
800-231-4222

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Back Cover

What is osteoporosis?

Bone section through hip

Normal bone

Osteoporosis

It is normal for bones to get weaker with age. Knowing how strong your bones are lets your health care provider help you to make your bones healthy.

Your bones have holes or spaces in them, which is normal. Osteoporosis is when these holes get bigger. This means a person's bones get thinner, weaker and can break easily.

Most people do not know they have osteoporosis because they cannot feel their bones getting weaker. Often the only sign is breaking a bone. This can cause pain. Most often, people with osteoporosis break bones in their back (spine), wrist, hip or arm. If you break a hip, you may need help to walk.

Improve Your Bone Health in 5 Steps!

STEP ONE

Call your health care provider today and make an appointment!

What is a T-score?

A DXA scan is also known as a Bone Mineral Density (BMD) test. A DXA scan is a test that shows your doctor how dense, or solid, your bones are. Your results are a T-score.

A T-score tells you how much your bone density compares to the bones of a healthy 30-year-old. At age 30, our bones are the strongest. The letter that came with this brochure has your T-score.

T-score range	Category
-1 and above	Normal Bone Density
Between -1 and -2.5	Low Bone Density
-2.5 and below	Osteoporosis

Take your letter and this brochure with you.

If you think of any questions jot them down here.

STEP TWO

Get the right amounts of calcium and vitamin D

Calcium

You need 1,200–1,600 mg daily. You can get this from food, pills or both.

Calcium-rich foods

Food	Serving Size	Calcium (mg per serving)
Milk (cow and soy)	1 cup (8 oz.)	300 -325
Ice Cream	1/2 cup (4 oz.)	150
Yogurt	1 cup (8 oz.)	400
Cheese	1-2 slices (1 oz.)	200
Fruit juice or cereal with added calcium	3/4 cup for juice 1 cup for cereal	300 or more (read label)

2 STEP TWO

Get the right amounts of calcium and vitamin D

Vitamin D

You need 800—1,000 IU daily. You can also get this from food, pills, the sun, or all three combined.

Vitamin D-rich foods

Food	Serving Size	Vitamin D (IU per serving)
Salmon	3.5 oz.	360
Tuna fish (canned)	1 can (4 oz.)	200
Milk	1 cup (8 oz.)	100
Orange juice	1 cup (8 oz.)	100

STEP TWO

Get the right amounts of calcium and vitamin D

What if I can't eat dairy or don't like it?

When you are shopping, look for foods marked "Added Calcium" or "Calcium Fortified". Some examples are bread, cereals, pastas and drinks.

Think about the calcium-rich foods you eat during a typical day and write them down. Share the list with your health care provider so he/she knows how much calcium you are getting from your diet.

Include foods from the list above plus any marked "Added Calcium"

1. _____
2. _____
3. _____
4. _____
5. _____

If you cannot get the right amount of calcium and vitamin D from your diet, talk to your health care provider about your need for supplements. Remember, before taking any supplements, vitamins or medicine, talk to your doctor.

Supplements

Many calcium pills have 500-600mg of calcium and 400-600 IU of vitamin D per serving (typically 1 serving=2 pills).

Talk to your doctor or pharmacist to see if you need calcium pills. Read the labels on the bottle to make sure you are getting the right amount.

Your body can only take in 600mg or less at one time. If you need all 1,200mg from pills, take 1 serving with breakfast and 1 serving with dinner.

Medications

There are medicines that can help make bones stronger. Most people with osteoporosis need medicine. If your letter says you have osteoporosis or your risk of breaking a bone is more than 20%, ask your health care provider if you need medicine to help your bones.

If you are already taking one of these medicines, talk to your doctor about your need to continue taking it.

You still need calcium and vitamin D even if you are taking a medicine for osteoporosis.

STEP THREE

Move your body!

Your bones get stronger when you make them work. Here are some activities to help build your bones and keep them strong. Do any of these at least 30 minutes a day, five days a week. You can break these into ten minute sessions.

Weight-bearing exercises

- Walking/Hiking
- Aerobics
- Golfing
- Tennis
- Stair climbing
- Dancing
- Yard work/Gardening

Muscle-strengthening exercises

- Lifting weights
(even heavy items like soup cans or milk jugs)
- Using resistance bands
- Lifting your own body weight
(like push-ups or crunches)
- Yoga
- Pilates

* To avoid injury, it is important to check with your health care provider before starting a new exercise program.

STEP THREE**Move your body!**

It can be hard to think about how to fit activity into your life. Doing just 5 minutes of activity at different times in the day is a great way to start. Here are some ideas:

- Park your car farther away and walk.
- Take the stairs instead of an elevator.
- During a commercial break, walk around the living room or lift heavy soup cans.

Activity can be fun too!

- Play sports with your friends:
Some examples are tennis, bowling or golf.
- Go dancing!
- Take an aerobics or yoga class at your local recreation center.

**What are some other ideas you have?
Share these with your health care
provider.**

1. _____
2. _____
3. _____
4. _____

STEP THREE

Move your body!

Falls

When you move your body, try to avoid falls. A fall can lead to a broken bone. Here are some things you can do to keep yourself from falling.

Inside your home:

- Remove loose cords and throw rugs.
- Keep floors clutter-free.
- Use handrails and keep stairs well lit.
- Keep a flashlight near your bed.
- Put rubber mats in bathtub and on porch steps.

Outside your home:

- Wear shoes with rubber soles.
- Use a backpack or fanny pack to have your hands free.
- Watch for slippery floors or steps.
- Look out for curbs and cracks.
- Don't walk outdoors in icy weather.

Fig. 4.
Sections from Bone Health Educational Brochure (Cover and Exercise Step)

Table 1

Description of PAADRN Aims and Hypotheses

Aims	Endpoints	Hypothesis
Aim 1. Assess the impact of the patient activation intervention on bone-related quality of care in adults who have undergone DXA.	<ul style="list-style-type: none"> • Use of pharmacotherapy and Calcium/Vitamin D among intervention and control patients with osteoporosis. • Use of pharmacotherapy and Calcium/Vitamin D among intervention and control patients with normal and low BMD. • Bone-related health behavior including smoking cessation, reduction in alcohol intake, and weight bearing exercise among intervention and control patients with all BMD results. 	<p>1a. Among patients with osteoporosis, the activation intervention will increase the rate of pharmacotherapy and Calcium/Vitamin D use as compared with usual care.</p> <p>1b. Among patients with normal and low bone density, the intervention will reduce potential overuse of pharmacotherapy but will increase appropriate use of Calcium/Vitamin D.</p> <p>1c. There will be no clinically relevant difference in the effectiveness of the intervention in improving bone-related care in important patient subgroups including men and women, older and younger adults, and blacks and whites.</p> <p>1d. The activation intervention will have no effect on important bone-related behavior change including smoking cessation, alcohol intake, and weight bearing exercise.</p>
Aim 2: Assess the impact of the patient activation intervention on patient satisfaction with their bone healthcare, quality of life, osteoporosis-specific knowledge and self-efficacy, and patient activation.	<ul style="list-style-type: none"> • Patient satisfaction with bone-related care among intervention and control patients. • Global quality of life among intervention and control patients. • Osteoporosis-specific knowledge among intervention and control patients. • Patients' accurate knowledge of their DXA results among intervention and control patients. • Patient activation and osteoporosis-specific knowledge among intervention and control patients. 	<p>2a. Patients receiving the intervention will demonstrate greater satisfaction with their osteoporosis-related care and communication with their provider, but no change in their overall health-related quality of life than patients receiving usual care.</p> <p>2b. Patients receiving the activation intervention will demonstrate greater osteoporosis-specific knowledge and self-efficacy than patients receiving usual care.</p> <p>2c. Patients with higher preferences for self-care will demonstrate greater response to the intervention as measured by increases in patient satisfaction, quality of life, osteoporosis knowledge, and self-efficacy than patients with lower preferences for self-care.</p>
Aim 3. Assess the cost-effectiveness of the patient activation intervention.	N/A	N/A

Table 2

Characteristics of the three PAADRN Study Sites

	University of Iowa Hospitals and Clinics	Kaiser Permanente of Georgia	University of Alabama at Birmingham
Estimated patient enrollment	1,328	2,895	3,278
Number of DXA clinics	1 site with 1 DXA unit	5 sites each with 1 DXA	1 site with 2 DXAs
Number of DXAs/year on PAADRN eligible patients	1,239	3,173	3,054
Description of usual care	Patients have ability to review DXA report via electronic web portal	Patients receive DXA results via mail 3–4 weeks post DXA	Osteoporosis specialty clinic for those referred
Type of healthcare system	University-based	Group model health maintenance organization	University-based
Racial characteristics of patient population	92.3% Caucasian 1.3% African-American 1.1% Hispanic 1.2% Asian	72.9% Caucasian 21.4% African-American 2.3% Hispanic 3.5% Asian	76.2% Caucasian 21.1% African-American 0.8% Hispanic 1.7% Asian
Demographic characteristics	Rural	Urban	Urban with rural surrounding areas

Table 3

Data collection instruments used at baseline, 12, & 52 week follow-up

	Baseline	12-Week	52-Week
Demographics	✓		
Health History (OP status, fracture history, co-morbidities)	✓		
Communication with provider after DXA		✓	✓
'Osteoporosis and You' (knowledge scale) [42]	✓	✓	✓
Health Habits (calcium/vitamin D, exercise, smoking, alcohol)	✓	✓	✓
Satisfaction with bone-related health care	✓	✓	✓
EQ-5D-3L™ (health-related quality of life) [43, 44]	✓	✓	✓
Krantz Health Opinion Survey (preference for self-treatment) [52]	✓		
Patient Activation Measure [46]	✓	✓	✓
Single-Item Literacy Screener [53]	✓		
Subjective Numeracy Scale [54]	✓		
Medication adherence	✓	✓	✓
Osteoporosis Health Belief Scale [55, 56]	✓	✓	✓
Osteoporosis Self-Efficacy Scale [45]	✓	✓	✓