**Renew Bone Health and Fitness: An Osteoporosis Prevention and Management Community Health Program**

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**Background**

“Renew Bone Health and Fitness” is an osteoporosis prevention and management program for postmenopausal women with osteoporosis, osteopenia, and those at increased risk for decreased bone mineral density. This program incorporates high-impact exercise, high-intensity resistance training, weight bearing aerobic exercise, balance exercises, and patient education strategies based on the Transtheoretical Model. This comprehensive program utilizes various outcome measures to assess bone mineral density, falls risk, and overall health-related quality of life before and after completion of the program. On the individual level, the Renew Bone Health and Fitness program aims to improve bone mineral density through physical activity, decrease an individual’s risk for fracture by improving balance and providing falls prevention education, and improve health-related quality of life. On the interpersonal and societal levels, this program aims to decrease caregiver burden and decrease financial burden on the healthcare system.

Literature suggests that both high-intensity resistance training and high-impact training is effective in improving bone mineral density and physical function in postmenopausal women with osteopenia and osteoporosis. These types of exercise were found to be safe for this population with no reported adverse events.1, 2 A few exercises shown to be effective in improving bone mineral density include deadlifts, overhead press, back squat, jump landings, and hopping.1, 3 Improvements in bone mineral density with high-intensity resistance training and high-impact training has been found to be significant at multiple sites including the femoral neck and lumbar spine.1, 2

Weight-bearing aerobic exercise will also be incorporated in the Renew Bone Health and Fitness program. Research suggests that brisk walking is effective in preventing the loss of bone mineral density in premenopausal women and improving bone mineral density in postmenopausal women with a diagnosis of osteoporosis.4, 5 Roghani et al5 suggest that weight-bearing aerobic exercise is effective in improving bone mineral density in postmenopausal women with osteoporosis, but using a weighted vest during aerobic training may lead to significantly greater improvements in balance, body composition, and bone mineral density compared to aerobic training without the vest.

Because people with decreased bone mineral density are more susceptible to fractures, balance training is essential to decrease falls risk in this population and decrease financial burden on the healthcare system. A systematic review and meta-analysis by Kam et al6 suggest that balance exercises such as tandem stance, obstacle courses, and tai chi are effective in reducing falls and fracture in individuals with osteopenia and osteoporosis. This study also notes that knee extensor strength is a determinant for static and dynamic balance in individuals with osteoporosis which highlights the importance of incorporating both strength training and balance training in a program designed for osteoporosis prevention and management.6

In addition to the exercise interventions listed above, it is essential to provide patients with education regarding the pathophysiology of osteoporosis, modifiable risk factors, nutrition, and strategies for preventing falls. This is crucial for reducing the risk of fractures and preventing the progression of disease in this population. The Renew Bone Health and Fitness program will use the Transtheoretical Model (TTM) for patient education interventions. The TTM proposes that health behavior change occurs through the progression of six stages of change including precontemplation, contemplation, preparation, action, maintenance, and termination. This model describes health behavior change as a dynamic process that is most effective when interventions are matched to the individual’s readiness for change (or stage of change).7 Educational interventions based on the TTM have proven to be effective in reducing osteoporosis-related behaviors in young women.8 Interventions should include education on osteoporosis pathophysiology, risks and complications of osteoporosis, importance of prevention, osteoporosis prevention methods, and risk factors for osteoporosis. Research suggests that educational interventions that use the TTM are useful in advancing the individual’s stage of change and improving self-efficacy.8 Renew Bone Health and Fitness will use educational interventions that are structured based on the TTM to assess readiness for change and identify individual barriers to behavior change. Patient education will be tailored to the specific stage of change that the individual is in and will focus on reducing modifiable risk factors.

Ultimately, tailoring community health program interventions improves the intended outcomes or behavior change by enhancing motivation, increasing saliency of the program, improving knowledge retention, and increasing the appropriateness of the program for a particular group.9, 10 To apply the TTM and improve patient outcomes, the Renew Bone Health and Fitness program will provide stage-specific exercise recommendations and education as well as work with patients to set individualized goals. By using the TTM, physical therapists will have a better understanding of the patient’s goals, barriers to change, readiness for change, and prognosis for change.8

The Renew Bone Health and Fitness program will be a referral-based program within the Raleigh, Durham, Cary, and Chapel Hill area focused on evidence-based interventions and assessment of various outcomes to track progress overtime. Participants will be required to have a dual-energy X-ray absorptiometry (DXA) scan by their physician prior to starting the program. DXA scans measure bone mineral density, are used to diagnose osteoporosis and osteopenia, and are helpful in tracking changes in bone mineral density overtime.11 The patient will also be asked a series of questions to categorize their risk for osteoporosis as “low”, “medium”, or “high”. Risk factors to be assessed include age, gender, family history of osteoporosis, hormone therapy history, alcohol consumption, smoking history, nutrition information (vitamin D and calcium intake), medications, and physical activity levels using the International Physical Activity Questionnaire Long Form (IPAQ).12 The patient’s history of falls (within the past year) will also be recorded. Stage of change as part of the TTM will be determined through patient interviews performed by a licensed physical therapist.

The Osteoporosis Assessment Questionnaire – Physical Function (OPAQ-PF) will be used to assess disease-specific health-related quality of life and ability to perform daily activities of physical function. This outcome measure is useful in assessing effectiveness of osteoporosis treatment.13 A study investigating the psychometric properties of the OPAQ-PF found excellent internal consistency (α = 0.974), good test-retest reliability (ICC = 0.933), and adequate sensitivity to change (1 SEM = 4.0; MDC90 = 9.6). The OPAQ-PF also has good construct validity as it is able to differentiate between patients with no recent fracture (> 6 weeks) and patients with recent fracture (< 6 weeks).13

The Activities-Specific Balance Confidence (ABC) Scale will be used to determine patient-reported balance confidence for specific functional activities. In older adults, the ABC Scale has excellent test-retest reliability (r= 0.92, p < 0.001) and excellent internal consistency (α = 0.96). For reference, geriatric females who completed a fall prevention group had a mean change of -1.1 on the ABC Scale.14

The Timed Up and Go (TUG) test will be used to assess falls risk and physical performance in participants. Literature suggests that TUG time predicts risk of major osteoporotic fracture and hip fracture in older adult women independent of clinical risk factors or bone mineral density.15 In this study, fracture incidence increased with increasing TUG time up to 12 seconds. Ultimately, researchers suggest a slow TUG time (> 12 seconds) indicates worse general health and increased fracture risk in older adult women.15 Similarly, another study in older adult women found that slow TUG time (> 10.2 seconds) was associated with higher risk of fracture compared to fast a fast TUG time (< 10.2 seconds).16 In community dwelling older adults, the TUG has excellent test-retest reliability (ICC = 0.97) and interrater reliability (ICC = 0.99).17 Additionally, the TUG has good validity as it is moderately associated with various performance measurements and is able to discriminate between fallers versus non-fallers.18

Lastly, the Berg Balance Scale (BBS) will be used to assess balance and track improvements in balance overtime. Wang et al19 found that the BBS has good internal consistency (α = 0.77), good interrater reliability (ICC = 0.87), and moderate correlation with the TUG (Spearman’s rho = -0.53) in community dwelling older adults. Therefore, it is adequate for measuring balance in this population. Shumway-Cook et al20 found that a BBS < 51 with a previous history of falls was predictive of falls and a BBS < 42 with no previous history of falls was predictive of falls in community dwelling older adults. A study including 99 female participants between the age of 40 and 75 years old found a mean BBS of 47.74 in women with osteopenia (n = 34) and a mean BBS of 51.65 in women with osteoporosis (n = 34).21

The Renew Bone Health and Fitness program is designed to tackle the significant problem of undertreatment for osteoporosis. This program seeks to employ evidence-based interventions in postmenopausal women to prevent decline in bone mineral density, reduce the risk for fractures, and enhance quality of life through activities such as strength training, aerobic exercise, balance training, patient education, and addressing modifiable risk factors. This program also seeks to decrease caregiver burden and decrease burden on the healthcare system by reducing healthcare expenses.22

**Program Goals**

The aim of the Renew Bone Health and Fitness program is to diminish the disease burden of osteoporosis in participants and improve their understanding of how to prevent or manage osteoporosis through behavior modification and physical activity. Success of the program after 12 weeks of participation will be measured based on the following goals:

1. Participants will increase their score on the OPAQ-PF by 10 or more points, so the change is considered clinically meaningful and statistically significant.13
2. Participants will improve their TUG score to less than 10.2 seconds which represents decreased risk for fall and major osteoporotic fracture in people with osteopenia and osteoporosis.15, 16
3. Participants will improve their BBS score to greater than 51/56 to reduce risk of falls and fracture.20, 21
4. Participants will demonstrate a 1.5 – 2% increase in hip BMD as measured by a DXA scan.3, 23

Further, individual goals will be set for patients during the 12-week program based on their impairments.

**Methods**

**Enrollment and Advertising**

1. Flyers will be provided to local primary care providers to advertise the Renew Bone Health and Fitness Program. Flyers will also be placed at local physical therapy clinics and other medical offices to promote the osteoporosis prevention and management program.
2. Referrals are required to participate in the program and will be provided by primary care providers. A DXA scan must be performed by a physician prior to the start of the program. Another DXA scan will be completed after participation in the program.
3. All applicants will be called for a screening to rule out contraindications to exercise, current fracture, and to explain the layout of the program.

**Participants and Location**

1. The Renew Bone Health and Fitness program will be a referral-based program at Duke Physical Therapy Outpatient Clinic at Douglas Street. The target population will primarily be postmenopausal women with osteopenia or osteoporosis living in the Durham, Cary, Chapel Hill, or Raleigh area.
2. The Renew Bone Health and Fitness program accepts 20 individuals for a 12-week program period, and there will be a total of two 12-week programs per calendar year. Referrals must be received 4 weeks prior to the start of the program date to allow time to schedule individual evaluation appointments.

**Personnel**

1. Orthopedic and neurologic physical therapists at Duke Physical Therapy Outpatient Clinic at Douglas Street will complete the evaluation appointments and exercise sessions for the program. The program will require 3 – 4 physical therapists to participate during the 12-week period.
2. Physicians, nutritionists, pharmacists, and physical therapists will lead the health education topic lectures on a volunteer basis.
3. Students, aides, spouses, and family members may assist in guarding during various exercise activities.

**Program Schedule and Interventions**

1. First, a general health assessment and evaluation will be performed by the physical therapist. This initial visit will be focused on recording baseline measures, outcomes assessment, assigning stage of change based on the transtheoretical model, motivational interviewing to identify barriers to behavior change, describing the layout of the program, setting patient goals, and answering the patient’s questions or concerns. Evaluation appointments will be 60 minutes. The following will be included in the initial health assessment and evaluation appointment:
	1. Demographic characteristics
		1. Age, gender, family history of osteoporosis, hormone therapy history, smoking history, alcohol consumption, nutrition information on Vitamin D and calcium intake, medication list, medication adherence, and fracture history
	2. Falls History
	3. Pain Level
	4. Vital Signs
	5. International Physical Activity Questionnaire Long Form (IPAQ)
	6. Activities-Specific Balance Confidence (ABC) Scale
	7. Osteoporosis Assessment Questionnaire – Physical Function (OPAQ-PF)
	8. Lower extremity and upper extremity active range of motion
	9. Lower extremity and upper extremity manual muscle test
	10. Timed Up and Go Test (TUG)
	11. Berg Balance Scale (BBS)
	12. Motivational interviewing to determine stage of change based on the TTM
	13. Patient goals for the 12-week program

The full assessment will be performed at evaluation and after 12 weeks of participation in the program. Outcome measures will also be re-assessed at the 6-week mark.

1. Frequency/Duration
	1. Participants will be in the clinic 3 times per week for a total of 12 weeks. Participants will have 2 exercise sessions for 60 minutes and 1 health education lecture for 60 minutes each week.
	2. A home exercise program (HEP) will be included for individuals to complete outside of the clinic on two additional days per week. Each participant’s HEP will be modified at week 6 based on patient progress. A new HEP will be provided at week 12 to encourage long-lasting change in participants.
	3. There will be a total of 12 health education lectures which will be taught by physical therapists, nutritionists, physicians, pharmacists, or other volunteers. These courses will occur in the evenings to accommodate for the schedules of the participants, therapists, and volunteers. Educational interventions will be provided to the whole group with the participants stage of change in mind, but educational materials and handouts will be tailored to the stage of change of individual participants. Ten competency questions will be asked at the end of each education session to ensure understanding. The health education topics are as follows:

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| **Week** | **Health Education Topic** |
| Week 1 | Osteoporosis pathophysiology |
| Week 2 | Risk factors of osteoporosis |
| Week 3 | Nutrition for prevention and management of osteoporosis |
| Week 4 | Risks and complications associated with osteoporosis |
| Week 5 | Importance of exercise in managing osteoporosis, good posture, and safe bending/lifting demonstrations |
| Week 6 | Participant evaluation of the program and individual goals review |
| Week 7 | Navigating online osteoporosis resources and finding support groups |
| Week 8 | Pharmacological treatment options for osteoporosis and hormone therapy |
| Week 9 | Falls prevention education |
| Week 10 | Re-evaluation of patient-goals and goal setting activity |
| Week 11 | Major takeaways from educational topics |
| Week 12 | Participant evaluation of the program |

* 1. There will be a total of 26 exercise sessions throughout the program that include a warmup, balance training, resistance training, high-impact activities, weight-bearing aerobic activity, and a cool down.
1. Interventions
	1. The first 1-2 weeks of training will include a ramp-up period to maintain patient safety and emphasize good body mechanics, especially for resistance training and high-impact training activities.1
	2. Warmup
		1. A 5-minute warmup will be performed at the beginning of all exercise sessions. The warmup will include dynamic stretching and body weight exercises.
	3. High-Intensity Resistance Training1
		1. Week 1-2 will be performed at 55-65% of 1RM 3 sets of 5 reps
		2. Week 2-6 will be performed at 75-80% of 1RM 4 sets of 5 reps
		3. Week 6-12 will be performed at 80-85% of 1RM 5 sets of 5 reps
		4. Examples of exercises include deadlifts, overhead press, bicep curls, back squat, rows, lunges, step ups, bench press, leg press, and calf raises.
	4. High-Intensity High-Impact Exercise1, 2
		1. Week 1-2 will be performed at 5-6/10 RPE 3 x 10 each
		2. Week 2-6 will be performed at 6-7/10 RPE 4 x 10 each
		3. Week 6-12 will be performed at 8/10 RPE 5 x 10 each
		4. Examples of exercises include vertical jump, jump landings, single leg hopping, jump roping, and squat jumps
	5. Weight Bearing Aerobic Exercise5
		1. Treadmill walking or overground walking will be performed at 65-80% of max HR with a weighted vest that is 5-8% of body weight.
	6. Balance training6
		1. Examples of exercises include obstacle course navigation, challenging different stances, changing surfaces, challenging balance with head turns or eyes closed, dynamic gait activities, and use of a tilt board or bosu ball.
	7. The following is an example of the program intervention schedule:

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| **Exercise Session Schedule** |
| 5-minute warmup20 minutes of high-intensity resistance training 10 minutes of high-intensity high-impact activity10 minutes of balance training15 minutes of weight bearing aerobic exercise with weighted vest |

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**Cost**

1. The Renew Bone Health and Fitness program is a self-pay program and will not be billed to insurance. The total cost of the 12-week program will be $435 ($145 per month). The program is set at this price to cover the cost of individual patient evaluations and group exercise sessions.
2. Health education sessions will also not be billed to insurance as these will be provided by volunteers within the healthcare profession.
3. Financial assistance applications will be available which may help cover part of the cost of the program.

**Program Evaluation**

The Renew Bone Health and Fitness program will be evaluated according to the CDC’s “Framework for Program Evaluation in Public Health” to systematically collect information and make judgements about the program, evaluate program effectiveness, and inform decisions about future program development.24 Program evaluation questions and outcome assessment will aim to address five questions:

1. Implementation – were the program activities implemented as intended?
2. Effectiveness – is the program achieving the goals and objectives originally set?
3. Efficiency – are the program activities being produced within budget and is the program feasible for staff?
4. Cost-effectiveness – does the program’s value and benefit outweigh the cost of implementation?
5. Attribution – can progress toward goals be attributed toward the activities in the program as opposed to other confounding variables?

Compliance to the program will be monitored throughout the duration of the 12-week period, and participants will be excluded from program analysis if their attendance is below 80%. Compliance to home exercise programs will also be monitored throughout the program via self-report data. Program evaluation will take place at two points over the course of the 12 weeks, specifically at the 6-week and 12-week mark. At these points, physical therapist will reassess outcome measures and participants will fill out a satisfaction survey and offer an open-ended evaluation of the program. Questions on the satisfaction survey will address the accessibility of the program for participants including factors such as transportation, location, cost, and time commitment. Participants will be able to provide their opinion on what they like about the program and what they think could be improved in the future. Participant feedback is essential to the development of the Renew Bone Health and Fitness program because 1) this program is in its infancy and 2) there are limited programs available that aim to address prevention and management of osteoporosis. Further, at the 10-week mark, the health education session for that week will be a re-evaluation of individual patient goals and a goal-setting activity for the remaining weeks in the program. This session will be useful for therapists to understand what patients state they are still struggling with, what areas they would like to improve in, and what barriers may prevent them from maintaining physical activity after the program has concluded. To ensure competency of patient educational information, a 10-question test will be given at the end of each education session. Answers will be reviewed and discussed with the group.

Cost-effectiveness of the program will be evaluated by comparing the net profit generated by program dues subtracted by average reimbursement for potential patient appointments that could have been scheduled by each therapist during that time. Twenty participants will be divided among 4 therapists so each therapist will be responsible for the initial evaluation of 5 patients. The responsibility for exercise sessions will rotate among therapists on a weekly basis. Each week, two physical therapists will jointly lead a 60-minute group session, so each therapist is responsible for leading one session per week. The participating physical therapists will review the program at the end of the 12-weeks to determine if they had sufficient equipment, resources, personnel, and if the program was feasible perform in addition to their normal caseload. Additionally, if participant feedback suggests cost is a limiting factor for individuals, the cost of the program will be reassessed, or the idea of fundraising and sponsorships will be discussed.

Effectiveness of the program will be assessed by outcome measures and other objective patient data that is collected during the evaluation appointments. By the end of the program, participants should increase their score on the OPAQ-PF by 10 or more points and increase their hip bone mineral density by 1.5 – 2% on their DXA scan to represent clinically meaningful change according to current literature.3, 13, 23 At the end of 12 weeks participants should also improve their TUG score to 10.2 seconds or less and improve their BBS to greater than 51/56 to reduce risk of falls and fracture.15, 16, 20, 21

Evaluation of program’s implementation, effectiveness, efficiency, cost-effectiveness, and attribution are imperative to help guide evidence-based decision making, allocation of resources, structure of the program, and other logistics. It is essential that feedback is provided from all participating stakeholders including volunteers, therapists, administrative staff, and participants.

**Conclusion**

Inadequate treatment for osteoporosis elevates the risk for fracture, disability, and mortality and leads to higher costs for individual patients and the healthcare system. Effective prevention and management of osteoporosis with the introduction of the Renew Bone Health and Fitness program will have significant impacts on individuals, families, and the community. This program incorporates evidence-based interventions such as strength training, aerobic exercise, balance training, patient education, and addressing modifiable risk factors to improve bone mineral density, reduce the risk of falls and fractures, decrease caregiver burden, reduce healthcare expenses, and enhance quality of life.25 The Renew Bone Health and Fitness program offers a cost-effective approach to address the undertreatment of osteoporosis. It is an innovative program designed to increase the accessibility of health education and exercise for individuals with osteoporosis, osteopenia, and decreased bone mineral density. This program partners with local primary care providers to deliver a wholistic treatment approach to encourage physical activity and promote positive behavior change. Additionally, this program allows community members to take an active role in their well-being.

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