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Use of pragmatic community-based interventions to enhance recruitment and adherence in a randomized trial of Tai Chi for osteopenic women: Insights from a qualitative sub-study

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Abstract

Objectives—To qualitatively evaluate the feasibility of utilizing a pragmatic network of community-based Tai Chi schools to deliver 9-month exercise interventions to osteopenic women and to explore the impact of this design feature on facilitators and barriers to trial recruitment and participant adherence during and following the trial.

Methods—Within a randomized trial comparing 9 months of Tai Chi plus usual care to usual care alone for post-menopausal women with moderately low bone mass, exit interviews were conducted with 43 participants randomized to the pragmatically-delivered Tai Chi intervention. Transcripts were digitally recorded, transcribed and imported into NVivo, a computer-assisted qualitative data analysis software. Qualitative content analysis was used to code the data. Patterns emerging from among the codes were further examined and clustered into themes.

Results—Analyses revealed features of pragmatically-delivered Tai Chi programs that both facilitated and impeded study participation and/or post trial adherence. Direct facilitators included: convenience of class locations and times, alternative learning modalities, quality of teaching, community and social support and perceived health benefits. Barriers consisted primarily of time-related issues. A possible causal mechanism--self-efficacy--was also identified.

Conclusions—Factors related to using pragmatically-delivered intervention were beneficial in fostering both study participation and post-trial adherence to the Tai Chi programs. The qualitative sub-study was valuable for identifying these factors and a possible causal mechanism. These

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findings will assist in the design and conduct of future studies exploring the use of Tai Chi in fracture prevention and health-related quality of life in post-menopausal women.

Keywords

Osteopenia; low bone mass; Tai Chi; fractures; pragmatic trials; qualitative methods; exercise adherence

Introduction

Fractures resulting from osteopenia (moderately low bone mineral density (BMD)) are associated with significant long-term morbidity and high medical costs.^{1, 2} An estimated 12 million Americans have osteoporosis and 40 million have osteopenia.³ While the absolute risk of fracture is higher in women with osteoporosis, the greater prevalence of osteopenia or moderately low BMD results in an overall greater number of fractures in women with this level of bone fragility.^{3, 4} Optimal interventions for osteopenic women are not yet well-defined.⁵ Long-term treatment with pharmacological therapy is not medically indicated in many women with moderately low BMD^{6–8} although current guidelines do include the recommendation for regular exercise.⁹ However, there is no consensus regarding the optimal types and regimens of exercise for treating moderately low BMD, or for addressing other fracture-related risk factors experienced by women with osteopenia (e.g. poor balance, decreased muscle strength).¹⁰ Moreover, long-term adherence with prescribed conventional exercise is typically low and decreases with age.^{11, 12}

Tai Chi (taiji, tai chi chuan or taijiquan) is a traditional Chinese mind-body exercise of growing popularity in the U.S. with potential as a safe, effective, low cost, and engaging life-long intervention for older women with low BMD. Tai Chi employs detailed regimens of physical movement, breathing techniques, and cognitive tools (e.g., focused somatic awareness, imagery) to strengthen, relax and integrate the body and mind.^{13, 14} Preliminary research suggests that Tai Chi may reduce falls and fracture-related risk factors;^{15–18} however, few rigorous randomized clinical trials (RCTs) have evaluated the effects of Tai Chi on attenuation of BMD loss and balance in osteopenic women.^{19–23}

Tai Chi practice is represented by many different styles (e.g., Yang, Wu, Chen, Sun), and within each style, a variety of choreographed exercise routines and training principles are emphasized. Moreover, studying the impact of Tai Chi on outcomes such as BMD, requires a relatively long period of exposure, posing challenges to recruitment and adherence. Because of this, clinical evaluation of Tai Chi poses unique methodological challenges regarding delivery and optimal choice of intervention and control groups for any given trial, and drawing generalizations across multiple studies. Pragmatically-delivered interventions embedded within randomized trials may be particularly informative for the study of complex interventions like Tai Chi.^{24, 25} Pragmatic trials vary in their design, but a key objective is evaluating the overall effectiveness of interventions as they are practiced in a 'real world' or natural setting.^{26, 27} Pragmatic trials generally compare the treatment of interest with an existing standard of care. MacPherson²⁸ summarizes a number of characteristics of pragmatic trials that make them well suited for multi-component therapies such as Tai Chi,

including: 1) testing of the overall ‘package’ of components in an intervention; 2) conducting the intervention in a natural setting; 3) accepting a diversity of implementations of the therapies under study according to their use in the community; and 4) high external validity. Because of the convenience afforded using interventions offered at a diversity of geographic locations and weekly class times, use of community based-schools also has the potential to enhance participant recruitment and long-term adherence, including both within-study compliance and post-trial adherence. Short-term clinical studies of Tai Chi (e.g., 12–24 weeks) commonly report high enjoyment and adherence rates,^{29–32} however, less is known about adherence in community-based Tai Chi trials and post-trial commitment to Tai Chi training.

We completed a pilot RCT comparing a 9-month program of Tai Chi combined with usual care to usual care alone in 86 postmenopausal osteopenic women. A unique feature of the trial was that Tai Chi instruction was pragmatically delivered utilizing pre-screened community-based Tai Chi programs to maximize external validity of results and enhance participant adherence.³³ Clinical findings reported elsewhere indicated that Tai Chi training offered through these programs was safe and showed trends towards reducing multiple fracture-related risk factors among participants, including attenuating BMD loss, improving fall-predictive postural control parameters, and reducing levels of serum bone turnover markers.³⁴ In this paper we summarize results of an embedded qualitative study based on exit interviews of study participants randomly assigned to Tai Chi. Specifically, we utilize qualitative outcomes to evaluate the following questions: 1) Is the use of a pragmatically-delivered Tai Chi intervention feasible and does it impact participants’ recruitment, retention and pre- and post-trial adherence to Tai Chi training and 2) what other factors, as described by study participants, influenced recruitment, retention and Tai Chi training adherence?

Methods

Details regarding study design are presented elsewhere.³⁴ A total of 86 post-menopausal osteopenic women were randomized in a 1:1 ratio to receive 9 months of Tai Chi training in addition to usual care, or to usual care alone (control group). Multiple institutional review boards approved this study. All recruitment and intervention protocols took place between September 2008 and January 2010.

Study population

Participants were recruited from a large network of Boston area clinics serving approximately 300,000 members. Inclusion criteria were: 1) Women ages 45–70y; 2) BMD T-scores of the femoral neck or trochanter and/or spine between –1.0 and –2.5; 3) post-menopausal without menses for 12 months; 4) exercise no more than 5 days a week on average for more than 60 minutes per day, and 5) no prior experience with Tai Chi. Detailed exclusion criteria are listed elsewhere.³⁴

Tai Chi Intervention

Participants randomized to the Tai Chi group received nine months of Tai Chi training in addition to usual care. All Tai Chi interventions were administered pragmatically at one of

seven pre-screened schools within the Greater Boston area that met specific guidelines described elsewhere.³³ Instructors were asked to teach using the same approach and protocols employed for non-study, community participants. Study participants were asked to attend a minimum of two classes per week for the first month, and one class per week for eight months thereafter (minimum class duration of one hour). They were asked to practice an additional two times per week during the first month, and three times per week thereafter (minimum of 30 minutes per session), which could be home practice or additional classes at their school. Thus, participants were asked to participate in Tai Chi training a total of 99.5 hours over the nine-month interventions.

Qualitative sub-study

A qualitative sub-study was embedded to explore which factors of a pragmatic approach to studying Tai Chi would help to foster greater participation and post-trial adherence. There are numerous benefits to using qualitative methods within a larger quantitative study. Qualitative research can expand upon quantitative results by providing information about abstract concepts difficult to measure quantitatively or by explaining unexpected findings from a quantitative analysis.³⁵ A qualitative approach can also help to uncover participant motivations as well as the relationships and causal mechanisms that underlie or influence behaviors and decision-making processes on both the individual and cohort level.^{36, 37} Consequently, it may be possible to use qualitative findings to inductively generate hypotheses that can be tested quantitatively.³⁸ In addition, it is possible to gain a better understanding of the impact of complex processes or interventions by qualitatively exploring the diverse beliefs and meanings that participants ascribe to these phenomena.³⁷ Finally, qualitative data obtained from study participants may help reveal factors influencing study participation including both challenges and benefits thus supporting the feasibility of conducting similar intervention research and guiding development of future studies.^{39, 40} Thus, qualitative research may be particularly well-suited to pragmatic research on complex and multi-faceted interventions like Tai Chi.

As part of the 9-month follow-up, participants in the Tai Chi only group responded to a qualitative survey consisting of six open-ended questions asking the women to describe their experiences with Tai Chi in their own words. The six questions were: 1) Has participation in this program had any noticeable effect on your life?; 2) Has participation in the program affected your activities of daily living in any way?; 3) Do you feel like you benefited from this program?; 4) Did you find the program enjoyable?; 5) Would you recommend Tai Chi to other women with low bone density?; 6) Do you plan to continue practice of Tai Chi?

Qualitative data management and analysis

All qualitative interviews were digitally recorded and transcribed verbatim by a research assistant; transcripts were imported into NVivo 9.2, a computer-assisted qualitative data analysis software (CAQDAS) program for storing, organizing, analyzing and retrieving data.⁴¹

Qualitative Description (QD) was the method used in the management and analysis of the data from the responses to the open-ended questions. QD uses a low-inference interpretation

to identify patterns and themes in the data resulting in a summary of an event or an experience expressed through the point of view and in the everyday language of the participants. QD is particularly useful when experiences of a phenomenon have not been fully described or when answers are needed for questions specific to clinical practice, policy or research including intervention development.^{42, 43}

The primary analytic method of this sub-study was Qualitative Content Analysis, a systematic coding and summarizing of data to explore emerging themes related to the study questions. Because findings are typically represented using terminology found within the text of the data, Qualitative Content Analysis is especially appropriate for QD.^{42, 43}

Texts were first read without applying any codes in order to obtain a sense of the whole experience.^{44, 45} After the initial reading, the texts were reread and coded line by line to identify similar words, phrases or other segments of text.⁴⁶ Text segments bearing the same codes were clustered and systematically organized^{46, 47} into more manageable segments, then further compressed into subcategories and finally themes.⁴⁸ Analysis of the texts continued in this iterative fashion until no new codes were found in the data.

Trustworthiness and Rigor

Trustworthiness or rigor in qualitative research is typically established through strategies that enhance quality and integrity. The use of a CAQDAS for organizing and analyzing the data was one strategy that enhanced quality while another strategy was that of investigator triangulation: two of the three authors analyzed the data and then compared coding decisions. Analytic collaboration can decrease the possibility that the analysis was unduly influenced by the biases of any one individual.⁴⁹

Results

Participant baseline characteristics

Forty-three women were randomized to the Tai Chi study arm. The average age of the participants was 60.4 years old (range 46–70y). Women were predominantly white (84%) and well educated (90% with college-level education). At baseline, most expressed high expectancy that Tai Chi would be beneficial for osteopenia.³⁴ Forty-two of 43 (98%) individuals completed baseline and 9-month follow-up protocols. Adherence with Tai Chi interventions was variable with twenty-six participants (60%) considered per protocol (defined as >70% class attendance and home practice). Average combined total training time (i.e., class plus home) over the 9-month intervention was 83.2 hours (median = 93.2 h; range = 0 to 226 h) for all participants randomized to Tai Chi and 120.6 hours (median = 107.3; range 82 to 226 h) for those who were per protocol. Interventions were administered at six of the seven pre-screened schools that were provided as options to participants, with 59% of those attending classes based on the Wu style of Tai Chi and 41% attending classes based on the Yang style of Tai Chi. Participant self reported satisfaction with their Tai Chi intervention was very high at 3 and 9 months.³⁴

Qualitative Themes

Through the analysis of the qualitative responses, one overarching theme, 'Facilitating Adherence' emerged. This theme captures multiple factors, as described by women in their interview responses, that contribute to study participation and post-trial continuation of Tai Chi. These factors will be described accompanied by illustrative participant quotations.

The primary factor impacting on both adherence to the study protocol as well as post-trial continuation was situating the classes in community-based schools. Using these schools provided women with multiple opportunities for Tai Chi practice. Unlike participants in studies where classes are held at one pre-determined location and time, the participants in this pragmatic study were allowed to choose a school from among those on the approved list. They could then attend a variety of classes at that school. The option of attending classes in locations and, perhaps more importantly, at times that were convenient, allowed some women to more easily participate in the requisite two classes per week. One woman reported, "It was helpful ...to go more than once a week. There were a couple times when I went three times" and another noted "...I found that I had the most success when I could just attend three classes a week...the only way that I could be consistent was by going to class two and three and I loved the fact that the registration covered multiple attendances."

Being able to attend classes at multiple and varied times over each week may also have fostered better learning: "...someone would be teaching me a new piece of a form and it just wasn't clicking and part of that might have been because it was close to 8 o'clock at night... Saturday morning classes I definitely felt a little brighter and better balanced too." One woman described the positive results of frequent class attendance: "I thought it was helpful...because when you left the first time [within a given week] if you didn't quite get it, the second time it was starting to feel cemented and...there were a couple of times when I went like three times...that helped because by that third time you really felt confident."

Community-based schools also allowed participants to learn from experienced Tai Chi masters deeply committed to their art. Women were enthusiastic and expressive as they praised the instructors for their expertise, describing them as 'wonderful' teachers who are 'passionate and committed' to helping others to learn Tai Chi. Instructors were seen as experts in their craft, possessed of a great measure of knowledge and authenticity, and willing to share their wisdom with students. The expertise of the instructors inspired both continued attendance as well as a desire to improve: "...they make you want to come. They challenge you...in a good way...they make you want to do well." Agreed another woman: "The teachers were really terrific. They really wanted people to succeed." Patience and providing support were also important characteristics of instructors: "They were very kind... very patient...It's what they really do...it was never an issue to go to class." Women also appreciated hearing information about the Tai Chi and the movements comprising each form: "...and what I loved, too, is how he would explain what was behind the movement, you know, why did you do something..." As summarized by one participant: "I really, really thought those were the best instructors ever..."

Traditional Tai Chi schools typically engage senior students to assist with teaching classes, creating a rich psychosocial support structure that also facilitated compliance. When study

participants experienced frustration or anxiety learning new steps in the Tai Chi form, they often found reassurance and direction from other students, adding to the overall experience of support: "...if you're standing there...particularly beginners, lost, someone will stop and help you. I mean, you know, a formal teacher or just someone else who has been there longer. It's the most supportive environment I've ever seen. It's terrific."

Local classes also afforded women the opportunity to meet and establish relationships with people in their neighborhoods, which may have served as an additional social incentive for attending class or practicing on a regular basis: "...I had the social interaction of, you know, meeting people there and hanging out a bit afterwards and chatting and that sort of thing. So that was all...very beneficial." Added another participant: "...it was enjoyable to have that kind of social connection as I was learning."

Women spoke of making new friends and being part of a community with their classmates. The experience was fun for many: "...there's a lot of laughter that goes on, and laughter certainly helps..." For some participants, the 'camaraderie of other women,' especially women 'of a certain age' as one participant stated, was an important component of their class experiences: "I was going to the Tuesday afternoon class every week...and the same people came almost all the time and so we, you know, we all knew each other and...and it was just a very pleasant social time, to socialize, with the other women..." One participant recounted actually practicing at home with several other women from the study, an experience quite likely made possible by situating the classes in community schools where women could more readily meet other study participants and class members who lived nearby: "...a couple of times I practiced with a small group. We had three of us in her living room practicing...That was fun. There were two other people in the Tai Chi study...we probably should have done that more often."

Another pragmatic design feature that supported adherence to the study protocol was providing an opportunity for women to do some of their Tai Chi training at home. Participants were given an instructional DVD by the Tai Chi schools that could be used to guide home practice. This option was very helpful when issues such as time constraints or weather precluded attendance at class: "I did find the DVD helpful and that's the only way I could possibly catch up. And I did do that at home even when I was missing classes. I don't know if I was doing it right but at least I was doing some of it." Several participants commented that they intended to continue their practice at home through use of the DVD: "I know I was going to continue at home and I do have the...DVD of it so I can practice on my own..." Some participants also planned to continue taking Tai Chi classes after the conclusion of the study either by enrolling in classes where they had taken their Tai Chi lessons or exploring other schools closer to home.

While the interview responses revealed factors that promoted adherence and continuation, factors that made study participation more burdensome also emerged. It is noteworthy that some of these barriers also served as facilitators. School location is an example of a factor that could exert opposing influences. Although situating the Tai Chi classes in local schools often helped to promote study enrollment, not all schools were convenient for all participants; hence for some individuals, Tai Chi practice waned in the latter months of the

study because of travel considerations: "I didn't like the commute. There was no easy way to get there without traffic...If it was down the street...I would have gone more frequently...probably would have continued."

Other influences on adherence, inherent to the study design, included time-related factors: time required for Tai Chi practice and the nine-month duration of the study; these factors posed opportunities for some, challenges for others. Tai Chi requires long-term consistent practice to become familiar with the choreography and benefit from the more subtle meditative therapeutic principles. Some women were drawn to this long-term study and frequent ongoing practice: "I do plan to continue because I think there's a whole lot more I need to learn...when they get into the second level, they refine the movements...So I think there'd be even more benefit as you become more and more aware of how each part of your body works." Others were less interested in making a long-term commitment to Tai Chi: "In order to master this I think you have to do this for years...it's almost like a lifetime thing...it's frustrating because in order to do it right you have to do it consistently...I don't have that dedication. I don't have that love for it. It's a little bit too slow paced for me..."

Study duration also contributed to making class attendance more difficult. Some participants had to make changes in their daily lives in order to be in the study; not all changes were positive: "On the negative side, it's the time spent has meant little less time for...art, music, a little less time, and that's what's taken the hit, and also other exercise activities have slowed down during this period." These modifications in women's daily routines became difficult to sustain over time: "...it's just the difficulty with the time...building it into my schedule...at the beginning I think I did a better job and then I kinda' faded." 'Not enough time' was a commonly-expressed reason for not continuing to take classes after the study ended.

Finally, cost was a factor. Having to pay for their own Tai Chi classes after the study ended was prohibitive for some participants. "I'd like to [continue classes], but the distance and the cost." Lamented one participant: "Because of the cost, that's the problem...I want to do it...I don't know how I'm going to do it. But I want to..." For some of these women, the DVD would serve as their means of maintaining their Tai Chi practice. In fact, while all the above factors impeded continued enrollment in a formal Tai Chi program, as previously noted, some participants were planning to continue their home practice with the DVD.

While the pragmatic delivery of the Tai Chi intervention was clearly an important factor promoting study feasibility, other factors also promoted study adherence; notable among these were the benefits that women derived from Tai Chi itself. One of the most commonly described changes occurring as a result of learning Tai Chi was improvement in balance. Participants frequently remarked as to how much better their balance was during class. This improvement extended beyond the Tai Chi lessons as women described real-life situations in which they had benefitted by better balance, for example, in their activities of daily living: "It helped with the balance (while) putting on a pair of slacks...I don't have to sit down to do it. I can do it standing." Better equilibrium also played a role in fall prevention as women were able to apply their Tai Chi knowledge and skills in treacherous situations: "My balance is a lot better...I feel more in control of my walking. And once I stumbled and regained my

balance so quickly which surprised me." Agreed another woman: "...my body has felt more together and able to handle either slipping on gravel or in the snow."

Participants also reported experiencing an increase in flexibility. They described feeling more limber and having less muscle and joint stiffness or tightness than prior to beginning their Tai Chi lessons. Less stiffness led to better posture: "I just feel physically better. I feel like I stand up better." Improved posture also resulted in part from women developing a better sense of their body's center: "...so with the tai chi you have to really think about it, strongly about it where your body is in space..." They were better able to make changes in how they stood and carried themselves: "I again will remember to, to hold myself up, not, not with tension but just, um, lightness and energy..." Perhaps because of this enhanced somatic consciousness, several women described having less hesitancy in their ability to move: "...I felt as though particularly when I was carrying things up and down these very narrow, curvy stairs that I had a little bit more confidence about my ability to, to manage that trip up and down..." This confidence carried over to other arenas as women reported feeling more confident about attempting other new challenges, such as a new type of exercise: "I wanted to try other things that I hadn't done in a while like the weightlifting... and I tried different exercise machines for the first time..."

Other health benefits included a reduction in pain related to less joint stiffness or postural imbalances: "I feel like I'm not plagued by all the back aches I used to get. I'd be at work and...I'd have this terrible back pain. I don't get that anymore". Some participants also experienced an increase in both energy and endurance for day-to-day activities as well as strength: "I feel stronger, I don't tire as easily." In addition, there were several reports of fewer headaches and improved sleep: "I was sleeping better and I can believe that some of it came from, I was doing tai chi in the evenings..." A few women noted an increase in mental alertness which they attributed to the need to memorize and recall the exact sequence of the movements of the form. Tai Chi was perceived to be a mental challenge or exercise, good for the 'aging brain' as one participant noted.

Tai Chi is not only a physical activity but also includes a mindfulness component. Therefore, attending Tai Chi classes often provided participants with an opportunity to relax both mentally and physically after a busy day: "But that [first] half an hour of the exercise... I could feel myself literally coming down and going from being hyper at work to coming down to a place and I guess people call it being centered." Many women remarked that they felt calmer and more relaxed mentally as a result of their Tai Chi practice: "its restful, it's dreamlike and yet you're working your body." Here again, this benefit extended beyond the classroom: "the other day when I got angry with my husband...I did deep breathing the way I learned in Tai Chi. I'm not so sure I didn't start ranting and raving afterwards but I did do deep breathing first!"

As has already been noted, women not only learned the Tai Chi form itself, they also learned how to apply and integrate this new knowledge into their everyday lives. Several women described making other lifestyle changes, such as increasing their daily activity level or making healthier eating habits, as a result of learning Tai Chi: "I am more aware of the fact

that I should maintain...a decent level of physical activity on a daily basis...I do make an effort to be physically active." Thus learning Tai Chi seemed to foster a healthier lifestyle.

There were very few negative outcomes reported. Most negative outcomes were issues such as finding the Tai Chi choreography frustrating to learn or feeling disappointment that it would take 'a lifetime commitment' to fully understand and develop mastery. A few participants admitted: "I still feel the same way I did nine months ago. I don't feel any different." Not all women liked the slow pace and lower intensity of Tai Chi and expressed their preference for engaging in more intense exercise such as lifting weights. In addition, the gentleness of the exercise led to a certain skepticism that it would not be intense enough to combat low bone mass and therefore could not be recommended to others for the purpose of improving BMD: "...there isn't really any strenuous physical activity...I wasn't sure how beneficial it's gonna' be. So, I'm not sure that I would recommend it..." Despite this skepticism, many women still strongly endorsed Tai Chi as a pleasant and relaxing exercise.

As this analysis of the qualitative data reveals, the pragmatic delivery of Tai Chi was a critical factor supporting adherence to the study protocol. Benefits derived from Tai Chi practice were also important influences on adherence and post-trial continuation.

Discussion

Exercise is increasingly recognized as an effective and cost-effective intervention for the prevention and rehabilitation of many age-related health concerns, including osteoporosis and fracture risk in postmenopausal women.^{6, 9} However, adherence to exercise programs, especially in older adults, is often poor.¹² Barriers to engaging older adults in exercise programs pose challenges for recruiting and retaining participants into clinical trials as well as for conducting research evaluating the promise of translating clinically tested interventions into sustainable community programs. These challenges have supported the continued search for novel, effective, lifelong engaging exercises, as well as alternative models of testing and delivery such interventions. The results of this qualitative study and its parent trial suggest that Tai Chi may offer an effective intervention for reducing fracture risks in women with moderately low BMD, and that utilizing a pragmatic community-based model for delivering the intervention may enhance recruitment, reduce loss to follow-up, improve adherence during clinical trials, and also increase post-trial commitment to Tai Chi.

Pragmatic trials are designed to reflect the real world in which an intervention takes place. In this study, the 'real-world' consisted of the community-located Tai Chi schools which provided multiple choices of classes and times, thereby increasing the likelihood that participants would be able to find classes convenient to their locale and schedule. The analysis of the qualitative surveys revealed multiple factors, most related to the pragmatic delivery of Tai Chi, that likely fostered better adherence to the study protocol: convenience of class locations and times, alternative learning modalities, quality of teaching, community and social support and perceived health benefits.

Some of these adherence-influencing factors have been observed in other studies. For example, in this sub-study, a high level of interpersonal interactions developed between

instructors and participants. Several qualitative studies exploring adherence have demonstrated that forming supportive bonds with instructors has a positive influence on adherence to a variety of interventions including exercise programs and medication regimens.^{50–53}

Similarly, social support may also foster better protocol adherence as noted in other studies.^{50, 52, 53} In this study, participant connection with other students may have motivated them to attend classes more frequently. Although some degree of both instructor and social support would have been inherent to predetermined cohorts and hospital-situated classes, the level of support in this study was enhanced by the community-based classes, thus underscoring the influence of the pragmatically delivered Tai Chi intervention.

In addition to the pragmatic design factors, the many health benefits derived from learning Tai Chi enhanced not only adherence but also post-trial continuation of Tai Chi training. Approximately 74% of the study participants indicated that they planned to continue their Tai Chi practice in some manner after the study. This is an important consideration in interventions for bone health that must be sustainable over time. In a qualitative study⁵⁴ looking at barriers and facilitators of exercise among individuals with arthritis, the authors noted that improved mobility, pain relief and other personally meaningful benefits were major motivators to exercise and most likely predictors of adherence.

The qualitative analysis also clearly illustrated that women integrated Tai Chi principles and benefits, such as balance, confidence and flexibility, beyond the classroom into their activities of daily living, a phenomenon that has also been observed in other studies.⁵² Real world application of Tai Chi is not only an important adjunct to fall prevention and therefore fracture risk reduction, but also provides women with additional feedback as to the benefits gleaned from Tai Chi practice. This feedback is critical because, unlike conditions such as arthritis, low bone mass usually has no symptoms making it difficult for women to perceive on an immediate basis that Tai Chi is beneficial for their bones. Instead, some other measure of benefit, such as better balance in real life situations and greater confidence of movement, may be necessary to foster long-term continuation of Tai Chi for the purpose of maintaining bone health.

The findings from this qualitative analysis point to at least one possible causal mechanism, self-efficacy, for fostering not only study adherence but also long-term continuation of Tai Chi practice. Self-efficacy has been associated with better adherence to health promotion behaviors. The factors in this study which improved adherence and continuation are frequently associated with self-efficacy. For example, greater frequency of exercise has been associated with higher exercise self-efficacy⁵⁵ which, in turn, is associated with adherence to long-term exercise programs.⁵⁶ This is especially true of Tai Chi wherein frequent and prolonged training is essential to fully learn and feel comfortable with the Tai Chi form. The conveniently located community-based schools and alternative instruction methods fostered more frequent Tai Chi practice which in turn may have led to greater sense of confidence or self-efficacy in one's ability to attend classes and progress through the Tai Chi form.

Other factors in this study that were linked to improved adherence and continuation, such as perceived health benefits and instructor and social support, have also been associated with self-efficacy.^{57–59} Not surprisingly, other studies have reported that Tai Chi can enhance exercise self-efficacy.^{30, 60–62} Thus self-efficacy may be an important causal mechanism for fostering not only study adherence but long-term continuation of Tai Chi practice. Identifying this possible causal mechanism allows for the use of theoretical models or frameworks which incorporate the concept of self-efficacy to support the development of further studies or interventions.⁶³

Several factors exerting a negative impact on adherence and continuation were also revealed through the qualitative analysis. Loss to follow-up in our 9 month Tai Chi intervention group was notably low (2%), with only one of 43 participants withdrawing. This is lower than average drop-out rates among other exercise studies with postmenopausal women.⁶⁴ However, compliance with Tai Chi exercise was not as high with only 60% (26/43) of participants being per protocol (defined as attending 70% of classes and doing 70% of prescribed home exercises). Lower compliance was partly due to broad societal economic downturns beginning in 2007. During this time, a number of participants lost their home and/or employment and could not devote time to study participation.

Low compliance was also related to other time-related issues: unclear expectations related to travel to, and participation in, classes, the duration of the study, and time to attain mastery of Tai Chi. These barriers again point to the role of self-efficacy as an underlying mechanism as time and complexity are factors that can influence perceived self-efficacy.⁶⁵ Based on lessons learned from this study, a second study evaluating Tai Chi for older adults using the same pragmatic network of Tai Chi Schools employed a simple ‘run-in’ phase that required all participants to travel to and observe Tai Chi classes in at least two locations before consenting and being enrolled in the study.⁶⁶ Increased familiarity with travel logistics and content of classes has resulted in modest improvements in compliance with 68% of participants in this second study per protocol over a six month intervention.

The qualitative findings also point to incorporating other study design strategies, such as including more schools and alternative options for practice, so that adhering to weekly Tai Chi practice requirements would not be as burdensome. For studies of longer duration, interval support or coaching,^{67, 68} may be helpful to maintain study participant motivation as well as inspire greater confidence or self-efficacy among participants as to their ability to complete the study protocol. In addition, information obtained during coaching sessions could provide further understanding as to when a participant's interest and motivation begin to wane, and what measures can be instituted proactively to prevent a decrease in adherence.

Our pragmatic intervention also affords practical advantages regarding recruitment. Because the majority of the community Tai Chi schools had rolling admissions or frequent start times for new students, our study could recruit subject throughout the year in a rolling admission fashion. This differs greatly from hospital-based randomized trials that require coordinating and screening sometimes large cohorts of potential participants that all need to be available to start at a common time and are all willing to meet at fixed times and a single fixed location. These advantages may translate into cost savings. Compared to our experience

with hospital-based trials in two previous clinical studies^{29, 69} in higher risk populations (e.g., heart failure, vestibulopathy, and COPD), we estimated per participant costs to be between 40% and 75% lower using a pragmatic approach (due to lower costs for Tai Chi instruction, parking, trial coordinator time, and other factors).

In addition to enhancing participant adherence to Tai Chi, the use of a pragmatic community-based intervention also has important conceptual advantages. Conceptually, use of a pragmatic intervention affords high generalizability and translatability into community-based programs. Because our Tai Chi intervention is not limited to a single protocol, but rather a range that is representative of Boston-based community programs, our results will have high external validity and should generalize to programs in most U.S. metropolitan areas.

Limitations

There are several limitations to this study that are important to acknowledge. First, because this is a qualitative study the results may not be generalizable to the wider population of women with low BMD. Secondly, the brevity of some of the interviews and responses limits the richness of the findings that can be inferred from the data. A third limitation is that interviews were conducted after women completed their classes and therefore recall bias may play a role in the recounting of their experiences. Also, because the interviews occurred only once, it is difficult to identify processes that took place over time, such as how women made decisions about participating and adhering to protocol or when Tai Chi skills and knowledge began to be integrated into daily activities. Clearly, more longitudinal qualitative information should be collected to better understand the complex processes fostering adherence to a long-term Tai Chi program and could be obtained through strategies such as ongoing diaries and interval interviews, grounded theory methodology or focus groups to promote obtaining a more comprehensive range of responses.

Another limiting factor in this study is that over 90% of the women were college educated which may play a role in a participant's beliefs and choices about health behaviors. However, the fact that these women were not exercising to a great extent at baseline is indicative of the fact that health beliefs are not always translated into health behaviors. Nonetheless, future studies should attempt to be more inclusive with regard to level of education. Future studies should also include more detailed information on comorbidities other than BMD, and how these health conditions impact adherence and compliance to pragmatically delivered Tai Chi. Finally, although participants had no prior Tai Chi experience, some had engaged in other mindfulness-related activities which may have influenced their experiences of and responses to Tai Chi. Future studies should specifically ask women about their past mindfulness activities to determine if indeed they may be a source of bias.

Conclusions

This qualitative sub-study demonstrated that a pragmatic design is feasible and can be instrumental in supporting enrollment, adherence and post-trial continuation of multi-faceted and complex interventions such as Tai Chi. In addition, incorporating qualitative research

into a pragmatic trial is beneficial for understanding meanings and processes that are not readily amenable to quantification. Further research is needed to ascertain the long-term impact of Tai Chi on fracture risk reduction as well as the sustainability of Tai Chi programs for osteopenic women in the community setting. This would be enhanced by a clinical trial study design that is pragmatic and employs multiple research methods and methodologies.

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