

A behavioral medicine intervention for community-dwelling older adults with chronic musculoskeletal pain: protocol for a randomized controlled trial

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Background: Chronic musculoskeletal pain is a major health problem among older adults, particularly those who live alone and/or those who are dependent on formal care. Chronic pain is associated with mobility problems, falls, fear of falling, catastrophizing thoughts, and a lower quality of life. Research shows that physical therapy interventions based on behavioral medicine approaches are beneficial for middle-aged adults with chronic pain. However, there appears to be no previous randomized controlled trials (RCTs) based on this theoretical framework that have examined the effect on older adults with chronic musculoskeletal pain who live alone at home and are dependent on formal care to manage their everyday lives. The aim of the planned study is to evaluate the effect of an individually tailored integrated physical therapy intervention based on a behavioral medicine approach compared with the effect of standard care.

Methods/design: The planned study is an RCT that will include one intervention and one control group involving a total of 150 adults aged ≥ 75 years with chronic musculoskeletal pain who live alone at home and are dependent on formal care to manage their everyday lives. The intervention will involve a 12-week home-based individually tailored intervention that will be designed to enhance the participants' ability to perform everyday activities by improving physical function and reducing pain-related disability and beliefs. The control group will be given standard care, including general advice about physical activity. The participants will be assessed at baseline and at 3 and 6 months after baseline. The primary outcome will be pain-related disability and physical performance.

Discussion: The intervention, if effective, will have the potential to be the basis of the first evidence-based guidelines for physical therapists who work with older adults with chronic musculoskeletal pain.

Keywords: fall, fear of falling, independence, physical activity, self-efficacy, quality of life

Background

In Norway, as in other countries around the world, care is oriented toward home-based services, with support from the community.¹⁻⁵ An important goal for the care of older people is to help them to maintain their ability to perform everyday activities, which is especially important for older community-dwelling adults who live with chronic pain.^{6,7} Everyday activities have been shown to be important for maintaining older individuals' independence and quality of life.^{8,9} Loss of the ability to perform everyday activities has been shown to be strongly associated with institutionalization, increased caregiver burden, higher resource use, and risk of death.^{10,11}

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Elderly individuals who live alone seem to be more vulnerable to health issues than those who live with others. Several studies have shown that individuals who live alone have poorer health, a higher degree of pain, greater disability with regard to the instrumental activities of daily living (I-ADL), a greater degree of functional decline, more falls, and more activity limitations related to the fear of falling. Living alone is also associated with a higher degree of mental illness (including symptoms of depression), and individuals who live alone report that they have a decreased quality of life compared to those who do not live alone.^{12–16} The majority of people who depend on formal help to manage their everyday lives live alone.⁴

As mentioned earlier, chronic pain is a major health problem among the elderly, especially among those who live alone. The prevalence of chronic pain among community-dwelling older adults ranges from 45% to 80%, and it is more common among women. The most common type of pain among older adults is chronic musculoskeletal pain.^{7,17}

Chronic pain among older people is associated with multiple pain-related issues, such as mobility problems, fatigue, social isolation, sleep disturbance, psychological distress, depression, and a lower quality of life.⁷ In addition, a recently published study showed that older people with chronic musculoskeletal pain have a substantially greater risk of developing a disability and impaired mobility performance over time compared to older adults without chronic pain.¹⁸ Similar results have also been found among older people receiving home care.¹⁷

Living with chronic musculoskeletal pain is also associated with psychological distress, that is, fear of movement and pain catastrophizing, and these beliefs have a strong influence on the development and maintenance of pain-related disability. Only in recent years, there has been a focus in this field on older people.^{19–21} Cederbom et al²² carried out a study that focused on community-dwelling older women with chronic pain who lived alone and were dependent on formal care, and they found that pain catastrophizing had a negative impact on both pain-related disability and psychological well-being.

Another major issue among older people is falling and fear of falling. Individuals who have chronic pain have been reported to have a greater risk of falling and a greater risk of developing a fear of falling.^{23,24} Despite this, there are few interventional studies on improving physical performance to reduce the risk of falling or on reducing the fear of falling, and there are fewer still among community-dwelling older adults with chronic pain.²³

Nevertheless, chronic pain among older people remains underassessed, underdiagnosed, and undertreated, despite its negative impact on physical and mental health, physical performance, and quality of life.^{25,26} Evidence-based guidelines for the treatment of chronic pain in community-dwelling older adults that focus on maintaining and improving physical independence, as well as improving general health and quality of life, are emerging for physical therapists who work with this population.

Interventions based on individually tailored integrated behavioral medicine approaches in physical therapy (BMPI) consider medical, physical, behavioral, cognitive, psychological, and social environmental factors in the analysis of the issues to be addressed and the subsequent treatment. These interventions have been shown to improve individuals' abilities to perform everyday activities and the level of physical activity among middle-aged patients with chronic pain.^{27–29} However, research on the effects of this kind of intervention for older adults remains inadequate. The only study that the authors have identified is a recently published feasibility study by Cederbom et al that involved a BMPI for older women with chronic pain who lived alone and were dependent on formal care.³⁰ The study found that the intervention was feasible for use in the target population and that the intervention was able to facilitate both physical activity and self-efficacy in relation to exercise and improved management of the participants' everyday lives.³⁰ However, Cederbom et al suggested that the intervention should be evaluated using a larger sample, with the goal of producing evidence-based guidelines for physical therapists.³⁰

Thus, the primary aim of the planned study is to evaluate the effects of an individually tailored integrated BMPI on pain-related disability and physical performance by comparing the effects to standard care among older adults with chronic musculoskeletal pain who live alone at home and depend on formal care to manage their everyday lives. The second aim of the planned study is to evaluate the effect of the intervention on pain severity, pain-related beliefs, physical activity levels, falls efficacy, number of falls, and health-related quality of life (HRQoL).

Methods/design

Overview of study design

The planned study is a pragmatic randomized controlled trial (RCT)^{31,32} with one intervention and one control group. The intervention is a 12-week home-based program. The intervention consists of an individually tailored BMPI that is intended to decrease pain-related disability and pain-related

beliefs (ie, fear of falling and pain catastrophizing) and improve physical performance and HRQoL, which could lead to an improved ability to perform everyday activities. The control group will be given standard care, which will include general advice about the benefits of physical activity in relation to pain problems. The sample will comprise ~150 participants who will be assessed at baseline and at 3 and 6 months after baseline.

A computer-generated, permuted-block randomization scheme with a 1:1 ratio between the intervention and control groups will be used,³² and the software program Stata 14 (StataCorp LLC, College Station, TX, USA) will be used to carry out the randomization. The randomization list will be prepared by a researcher who will not be involved in the remainder of the project. Sequentially numbered opaque sealed envelopes providing details regarding the group allocation will be prepared for each participant by a researcher who will not be involved in enrolling the participants. The randomization of each participant will be carried out after the baseline assessment, which means that the assessor at each baseline assessment will not know which group the participant will be placed in, and the assessors at the follow-up assessments will also be blind to the group allocation.

The study design follows the criteria set out in the CONSORT statement for reporting RCTs,³² and the protocol follows the Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) 2013 statement.³³ The planned study is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) under the identifier NCT02953470. Enrollment into the study is to start in autumn 2017, and it is likely that it will be finished by the end of 2018. The intervention will be ongoing during the same time interval. Data collection will last for 6 months after enrollment of each participant. Thereafter, the authors will write up and publish peer-reviewed articles based on the results of the RCT.

Study population

The trial will be conducted in 5–15 districts in the municipality of Oslo in Norway. The study will include the districts that are nearest to the city center. These districts represent both high- and low-income populations with varying education levels. The inclusion criteria will be as follows:

- being aged ≥ 75 years;
- living alone in ordinary housing;
- being dependent on home help services for individual care, housekeeping activities, and/or for medical needs but not being dependent on formal care (regarding ADL)

as a result of a moderate or higher degree of cognitive impairment (as assessed based on the data in the municipal registry);

- having musculoskeletal pain for ≥ 3 months;
- ability to walk independently indoors, with or without a walking aid;
- ability to understand and speak Norwegian;
- ability to fill in an activity diary or have contact with someone who can help to fill in the diary.

The exclusion criteria will be as follows:

- having ongoing physiotherapy treatment for injury/illness;
- receiving palliative treatment;
- experienced heart failure in the past 3 months.

The names and addresses of potential participants will be collected from a municipal registry that records the details of older adults who receive support from the municipality.

Ethics approval and consent to participate

The Regional Committee for Medical Research Ethics Norway has approved the planned study (reference number 2016/859). Each participant will receive oral and written information about the study, and they will be informed that their participation would be voluntary and that they would be able to withdraw from the study at any time. Before inclusion into the study, the participants will be asked for their oral and written informed consent.

Intervention and control groups

Both groups will receive general oral and written advice about physical activity during the first visit based on recommendations for physical activity for older adults aged ≥ 65 years devised by the World Health Organization and American College of Sports Medicine.^{34,35} The participants will also receive information about the known benefits of physical activity in relation to the effects of activity on pain problems.³⁶

Individually tailored integrated behavioral medicine in physical therapy intervention

The design of the BMPI is characterized by systematic consideration of the participants' physical and psychological conditions and the social and physical environmental factors related to the treatment goal. To identify each participant's treatment goal, a functional behavioral analysis (FBA) will be carried out by a physical therapist – together with the participant – in order to identify either a problematic everyday activity or an activ-

ity that it is highly important to maintain. The FBA includes identifying the physical, psychological, and environmental factors that inhibit and/or promote the participant's ability to perform the activity. The chosen activity is known as the "goal behavior," and it is designed to be "SMART," which means it is a specific measurable activity based on a limited time. FBAs are based mainly on the concept of "operant conditioning," the concept of how behavior is controlled by the consequences of the behavior." With an FBA as a base, an individual's skills that require improvement can be identified, whether these are physical, behavioral, cognitive, or social skills.^{37,38} Examples of goal behavior for the target population are as follows: to climb stairs safely, to be able to stand without physical support when doing the washing up, and to maintain the ability to walk indoors without a walking aid. The FBA also involves identifying an individual's thoughts about the short- and long-term consequences of not changing their behavior. The FBAs result in the formulation of a hypothesis regarding the relationships between the physical, psychological, and environmental factors that influence the goal behavior.

A key factor in reaching the treatment goal is to increase the participant's physical exercise levels, in line with a statement from the American Geriatric Society that specified that interventions concerning physical exercise should be part of the care provided to older adults with chronic pain.³⁶ The type of exercise that will be used to improve the physical issues experienced by each participant is functional exercise. The number and intensity of exercise sessions will be based on how much the participant is able and wants to do, and the number and intensity will increase progressively according to changes in the participant's performance and health status.³⁹

Another key factor of the intervention is to enhance and improve self-efficacy in relation to the goal behavior.³⁸ As described by Albert Bandura, "self-efficacy" is a central concept in social cognitive theory that refers to the strength of one's beliefs in one's ability to complete tasks (using specific behavior) in order to achieve specific goals.⁴⁰ Self-efficacy is an important factor if an individual is to achieve some form of behavioral change, for example, an increase in his or her physical activity levels. Self-efficacy beliefs also play an important role in embracing a new behavior, generalizing the new behavior to other situations, and maintaining the altered behavior over time.⁴¹ A low degree of self-efficacy also seems to be associated with chronic pain, pain-related disability, and depression among older adults living with pain.⁴² The evidence regarding the role that self-efficacy plays in various contexts is extensive, and it includes evidence regarding self-efficacy's positive effects on physical performance, the management of the psychological aspects of pain, and pain-related disability.²⁵

During the intervention period, each participant will receive visits from a physical therapist once a week for weeks 1–8 and 12. In week 10, the participant will receive support during a single telephone call. The content of the visits will be as follows: sessions 1–2: identification of a problematic or an important everyday activity that has to be maintained, and provision of advice about physical activity and information about how to fill in the activity diary. Performing an FBA, including goal setting and discussing how to carry out the physical activity and the intensity of the activity. Sessions 3–5: training in basic physical and psychological skills, for example, strengthening self-efficacy in relation to the goal behavior and decreasing fear of falling, catastrophizing thoughts, or fear of movement with regard to the goal behavior. Sessions 6–9: training in how to apply basic skills effectively to achieve the goal behavior, application of basic and more complex skills to other behaviors, and starting with secondary activity goals. Discussion of strategies for maintaining the new behavior. Discussion of problem-solving strategies, ie, how the participant could prevent and address new problems related to the goal behavior (in relation to being physically active) that may arise.

Control group

The control group will receive standard care, which will comprise one visit from a physical therapist who will give general oral and written advice regarding physical activity. Furthermore, the control group will receive telephone calls once a week from a physiotherapist during weeks 1–8 and 10, in the same order as the individuals in the intervention group will receive visits from a physiotherapist. The telephone call will consist of a reminder to be physically active in accordance with the advice given during the first visit. No advice on specific exercises will be given.

Training of the intervention providers

The project leader (who holds a PhD) and is a physical therapist (who is thoroughly trained and has comprehensive knowledge and competence regarding BMPIs), and research assistants (who are all physical therapists) will be involved in the recruitment and data collection. The assistants will receive education about the theoretical framework behind the study and the BMPI, and training in performing the data collection procedures, as well as delivering the intervention. To ensure that the data collection is performed consistently, the project leader will carry out a single baseline assessment with each assistant at the beginning. The assistants will receive regular supervision by the project leader during the intervention and data collection period so that they can discuss any issues related to the project.

Adherence

The participants in the intervention group will be asked to carry out general physical activity on ≥ 5 days per week, to carry out exercises related to their goal behavior on ≥ 5 days per week, and to attempt to carry out the goal behavior on ≥ 1 day per week. Adherence will be checked using the participants' activity diaries.

Adverse events

Adverse events will be recorded in the following four categories: falls, cardiovascular events, musculoskeletal injuries, and use of health care facilities. Issues related to the feasibility of the study procedure and the intervention protocol will be recorded in field notes during the intervention. The field notes will include comments about the time needed to collect the data, adherence to the study procedure and intervention protocol, and issues that arise in relation to the study procedure and intervention protocol.

Outcomes

Chronic pain is a multidimensional experience and, therefore, multiple outcomes will be used to detect potential changes. The participants will be assessed at baseline and at 3 months (follow-up 1) and 6 months (follow-up 2) after baseline. Table 1 provides an overview of the outcomes and assessment timepoints.

At baseline, the following demographic data will be collected: age (years), gender, marital status, amount of help from home help services and/or home health care services, use of walking aids indoors and outdoors, ability to get outdoors, number of self-reported medical diagnoses, self-reported use of prescribed and non-prescribed pain medication, number of years with pain, number of falls last year, and whether the participant feels as physically active as they wish to be.

The assessments will be interview administrated, and they will be conducted in a standardized way, which means that all the assessments for each participant will be carried out in the same order.

Primary outcomes

The primary outcomes will be pain-related disability and physical performance. Pain-related disability will be measured using the pain-related interference scale in the short Norwegian version of the brief pain inventory (BPI).^{43,44} The BPI is a self-report pain assessment tool that requires the respondent to report their pain severity and disability related to seven functions.⁴⁴ The pain-related interference scale involved seven items that assess the interference of the respondent's pain with general activity, mood, walking ability, normal work, relationships with other people, sleep, and enjoyment of life. The response alternatives are based on numerical rating scales

Table 1 Summary of outcomes

Outcome	Data collection measurements	Timepoints		
		Baseline	Follow-up 1 (3 months)	Follow-up 2 (6 months)
Primary outcomes				
Pain-related disability	Pain-related interference scale in the brief pain inventory	X	X	X
Physical performance	Short physical performance battery	X	X	X
Secondary outcomes				
Pain severity	Pain severity scale in the brief pain inventory	X	X	X
Pain catastrophizing	Two items from the coping strategies questionnaire	X	X	X
Falls-efficacy	Falls efficacy scale-international	X	X	X
Level of physical activity	6-point scale	X	X	X
Health-related quality of life	12-item Short-Form Health Survey	X	X	X
Assessment of perceived result	Consumer questions		X	X
Self-efficacy in relation to goal behavior (for the intervention group)	4-point scale	X	X	
Reached goal behavior (for intervention group)	Yes/no question		X	
Number of falls	Question on how many falls occurred last year, during the intervention period, and between follow-up 1 and follow-up 2	X	X	X

from 0 to 10, where 0 represents “does not interfere” and 10 represents “interferes completely.” The BPI has been validated for use in older adults with noncancer pain.⁴⁵

Physical function will be measured using the Norwegian version of the Short Physical Performance Battery (SPPB).^{46,47} The SPPB evaluates balance, mobility, and muscle strength by examining an individual’s ability to stand with their feet side by side, in a semi-tandem position, and in a tandem position, the time taken to walk 3 m, and the time taken to rise from a chair and return to a seated position five times. Each of the three tests is given a score, based on performance, between 0 and 4, which sum to a maximum score of 12 for the individuals who performed the three activities at the highest level of performance. The SPPB has been shown to be a reliable and valid measure of lower extremity performance, and it is therefore suitable for evaluating physical performance.⁴⁶

Secondary outcomes

The study will include several secondary outcomes. First, the severity of the pain will be measured by using the pain severity items in the BPI (see the “Primary outcomes” section regarding the BPI). The BPI pain severity scale involves measuring the highest, lowest, and mean pain intensity related to four items (usually with respect to the current intensity and the intensity during the past 24 hours or past week, and intensity now). The response for each item is bounded by the words “no pain” and “worst pain you can imagine.”

Pain catastrophizing will be measured by using the following two items from the Norwegian version of the Coping Strategies Questionnaire: “It is terrible and I feel it is never going to get any better” and “I feel I can’t stand it anymore.”^{48,49} The response scale ranges from 0 to 6, where 0 is defined as “never think that way” and 6 is defined as “always think that way.” The two-item scale has been shown to be both valid and reliable for use in adults who report having chronic pain.⁴⁸

Falls efficacy will be assessed using the Norwegian version of the Falls Efficacy Scale-International (FES-I).^{50,51} The FES-I assesses the level of concern about falling for 16 activities of daily living, with each assessment being based on a 4-point scale. Scores range from 16 to 64, with higher scores indicating greater concern about falling. The FES-I has been shown to be both a valid and reliable measure for use in older people.^{30,51}

The level of physical activity, including housekeeping activities, will be measured by using a 6-point scale.⁵² The response scale ranges from levels 1 to 6, where level 1 is defined as “hardly any physical activity” and level 6 is defined

as “hard exercise several times a week.” The scale has been shown to be valid for use in older adults.⁵³

HRQoL will be measured by using the Norwegian version of the 12-item Short-Form Health Survey (SF-12), which is a shortened version of the 36-item Short-Form Health Survey (SF-36). The SF-12 covers 8-HRQoL domains: 1) physical functioning (2 items); 2) role-physical, which is role limitations due to physical problems (2 items); 3) bodily pain (1 item); 4) general health (1 item); 5) vitality (1 item); 6) social functioning (1 item); 7) role-emotional, which is role limitations due to emotional problems (2 items); and 8) mental health (2 items). Based on these domains, summary scores for the physical component (domains 1–4) and mental component (domains 5–8) will be computed.^{54,55} The SF-12 has been shown to be valid for use in older adults.⁵⁶

To assess the participants’ perception of the results of the intervention, the following “consumer questions” will be asked:

- how is your physical activity level now, after participation in the study?;
- overall, how do you manage your everyday life compared with how it was before the intervention?;
- are you using what you learned during the intervention to manage your physical issues or prevent further physical issues?;
- do you take any pain medication?;
- have you been in contact with a physical therapist during the intervention period or since you finished participation in the study?³⁰

In addition, at follow-up 2, the following question will be asked:

- do you still exercise or are you being physically active?.

Regarding falls, the participants will be asked if they had any falls during the intervention period or between follow-up 1 and follow-up 2. In addition, for the participants in the intervention group, whether or not the goal behavior has been reached and the participants’ self-efficacy in relation to the goal behavior will be assessed.

Sample size calculation and statistical analyses

Power calculation was carried out for both primary outcomes, but there was no difference in the sample sizes calculated. The sample size calculation was based on a small meaningful change in the BPI and SPPB. For the BPI, a small meaningful change has been defined as a mean (SD) of 1 (0.5) points.⁵⁷ For the SPPB, a small meaningful change has been defined as

a mean (SD) of 0.5 (1.48) points.⁵⁸ To detect this effect when the power is 80% and the significance level (α) is 0.05, a sample size of 138 participants (69 in each group) would be needed (based on the size of a small meaningful change for the BPI or SPPB). We will include 150 participants in order to compensate for potential dropouts.

The data will all be analyzed and presented in accordance with the CONSORT statement for reporting parallel-group RCTs.³² Differences between groups will be analyzed with independent samples *t*-tests and differences between groups will be analyzed with paired samples *t*-tests. Intention-to-treat approach and missing data will be dealt with by carrying the last known values forward. Effect sizes will be calculated. If possible, further analyses will be carried out to examine relationships and/or correlations.⁵⁹ The significance level will be set at $P < 0.05$.

Discussion

It is believed that the planned study will be the first RCT to evaluate the effect of an evidence-based BMPI for older adults with chronic musculoskeletal pain. Should the intervention be shown to be effective, it could have positive effects both for older adults with chronic pain and for the practitioners who work with this population, and the study could make an important contribution to the evidence base.

We expect that the intervention described in this protocol will reduce pain-related disability and beliefs and increase physical performance and physical activity levels compared to the provision of basic advice about physical activity and reminder by telephone to follow the advice. The intervention may maintain or improve each participant's ability to perform everyday activities and their quality of life. In turn, this may allow the participants to live at home for longer. The results of the intervention will have the potential to promote evidence-based decision making among health practitioners and patients. The intervention will be home-based, as earlier studies have found this to be a successful approach for improving both participation and adherence in interventional studies with older people.^{30,60}

Regarding physical activity, we know that older adults with chronic pain are less physically active compared to older adults without pain. In addition, older people who live alone are less physically active than those who live with someone, and older women are less physically active than older men.^{26,38,61} A low level of physical activity can endanger health, independence, and quality of life.⁶¹ To promote increased physical activity levels and to increase the positive effects that physical activity brings about, the planned study will have a special focus on physical activity.

The intervention has been designed to enhance the participants' desire to be physically active for ≥ 30 min/day, in line with the World Health Organization and American College of Sports Medicine recommendations.³⁴

Individually tailored interventions can be challenging because of the variety of the interventions, but they may also be the most effective interventions, and they are recommended for use when carrying out interventions among older adults.⁶² A BMPI is a complex intervention, and those involved in implementing a BMPI require a comprehensive education regarding its multidimensional perspectives and the steps needed for the BMPI to succeed.^{26,38} The assistants who are to be involved in the study will be fully trained and they will have regular supervision by the project leader, who has the knowledge and competence to carry out this type of intervention.

From a scientific perspective, regardless of whether the results of the study are positive or negative, the results will contribute to knowledge about the effects of BMPIs in the target population, which in itself will be very interesting. If the results are positive, they might become the basis for evidence-based guidelines for managing chronic pain in the target population.

Before implementing an RCT, it is important to consider issues related to the quality of the study, including internal and external validity. To increase the internal and external validity, a systematic approach (based on guidance on designing and evaluating the quality of RCTs) has been followed.³²

To increase the potential of the study to contribute to evidence-based guidelines for health practitioners, the study has a pragmatic design. The pragmatic design will not only allow us to obtain valuable data with a high degree of external validity but also lay the foundation for producing potentially clinically applicable findings.³¹ Community-dwelling older adults were selected as the target population in order to assess the intervention using realistic conditions. The inclusion criteria were designed to encompass a representative group of participants.⁶³ In addition, the high-risk nature of the target population might enhance the adverse event detection rates. The intervention has been well described and the outcome measures were selected carefully so that they will be easy for the assessors to use and the participants to understand.

The outcome measures have been used previously among community-dwelling older adults with chronic musculoskeletal pain, and they have been shown to be both reliable and valid in the target population. To maximize the test-retest reliability, the assessors will be experienced physical therapists who will be comprehensively trained in how to carry out assessments before enrollment begins. Due to its large sample size and the strong theoretical basis of the

intervention, the planned study has the potential to generate new knowledge that may improve the design of future interventions for community-dwelling older adults with chronic musculoskeletal pain.

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Author contributions

SC conceived of the study. SC, ED, and AB participated in the design of the study. SC, together with a statistician, calculated the required sample size, and SC, ED, and AB developed the plan for the statistical analysis of the trial outcomes. SC will be responsible for the trial management, recruitment, and data collection. SC drafted the manuscript with contributions from all the other authors. All the authors have read and approved the final manuscript.

Disclosure

The authors report no conflicts of interest in this work.

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