

# Effects on Physical Functioning and Fear of Falling of a 3-Week Balneotherapy Program Alone or Associated with a Physical Activity and Educational Program in Older Adult Fallers: A Randomized-Controlled Trial

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**Background:** The effects on gait and posture of balneotherapy in fallers are unknown. We assessed the effects on physical functioning and fear of falling of a balneotherapy program alone or combined with a physical activity and educational program in older adult fallers.

**Methods:** A multicenter randomized controlled trial enrolled patients aged 65 or older referred to a 3-week balneotherapy program, and screened for risk of falling (a history of falls in the last year and a timed up and go test or a five chair rising test >12 sec or a 4-meter walk test >4 sec). In addition to balneotherapy, patients had either no intervention (controls) or twelve 60-minute sessions of physical activity including 15 minutes of health education and three 90-minute sessions of an educational program (intervention).

**Results:** There were 118 control and 105 intervention patients. The balneotherapy program alone had a clinically significant effect on (i) the grip strength, (ii) the five chair rising test, (iii) the 4-meter walk test, and (iv) the short physical performance battery (Cohen's  $d$  0.29–0.46). It had no effect on (i) the maximum time stood on one foot, and (ii) the timed up and go test. Furthermore, it worsened the falls efficacy scale ( $d = 0.27$ ). Adding a physical activity and educational program significantly improved (i) the time stood on one foot (Cohen's  $d = -0.34$ ), and (ii) the timed up and go test ( $d = -0.44$ ), (iii) and reduced the concern about falling (Falls Efficacy scale,  $d = -0.25$ ), and (iv) the fear of falling ( $d = -0.34$ ).

**Conclusion:** Older patients referred to a balneotherapy program and at high risk of falling when screened at the entrance of the center should be offered an additional physical and educational program to further improve the functional effects of balneotherapy on the timed up and go test, balance, and the fear of falling.

**Keywords:** balneotherapy, falls, physical activity, educational program, fear of falling, physical performances

## Introduction

Balneotherapy is defined as bathing in natural mineral or thermal waters. It has long been extended to include the use of mud baths. The therapeutic role of mineral elements and other chemical compounds in mineral waters justifies various medical indications.<sup>1</sup> Many studies have observed the positive effects of balneotherapy programs on the physical functioning of patients suffering from (i) rheumatoid arthritis,<sup>2</sup> (ii) chronic low back pain,<sup>3</sup> (iii) osteoarthritis,<sup>4</sup> or (iv)

fibromyalgia.<sup>5</sup> In France, balneotherapy is reimbursed by the national social insurance (*sécurité sociale*) when prescribed by a medical doctor in the case of a chronic disease sufficiently painful or invalidating to reduce physical functioning. To the best of our knowledge, there are no previous studies assessing the effects on muscle strength, walking speed, balance, and the concern about/fear of falling of a usual balneotherapy program alone or combined with a fall prevention physical activity and educational program when the chronic disease for which the balneotherapy program has been prescribed is so invalidating that it induces falls.

Prevention of falls is considered as a health priority since falls and fall-related injuries (i) have negative effects on functional independence and quality of life in older persons, and (ii) are associated with increased mortality and health-related costs.<sup>6</sup> Some factors such as the fear of falling, low gait speed, low muscle strength, an extended timed up and go test, and obesity all increase the risk of incident falls.<sup>6,7</sup> Exercise interventions aimed at improving balance and muscle strength are associated with a statistically significant reduction in falls, individual risk of one or more falls, and injurious falls.<sup>8</sup> Even if the effects of fall educational programs on falls incidence remain more uncertain,<sup>9</sup> the recent world guidelines for falls prevention and management for older adults recommend both physical activity and educational programs for reducing falls.<sup>6</sup>

It has been estimated that the year preceding a balneotherapy program, more than one-third of older patients experienced at least one fall, and that over 10% suffered a serious fall-related injury.<sup>10</sup> This makes thermal centers ideal places (i) for screening patients at risk of falls and (ii) for proposing interventions to reduce the falls risk factors. Our first hypothesis was that a usual balneotherapy program prescribed for a painful or invalidating chronic disease may improve muscle strength and walking speed but not balance, and is not able to reduce the concern about and fear of falling when the chronic disease is sufficiently invalidating to induce falls. Our second hypothesis was that adding a fall prevention physical activity and educational program to the balneotherapy program in patients screened at high risk of falling at the entrance of the center may further improve balance and reduce the concern about and fear of falling.

The main objective of this multicenter randomized trial was to evaluate, in older patients screened for risk of falling at the beginning of a 3-week balneotherapy program, the benefits of a standard balneotherapy program alone or combined with a fall prevention physical activity and educational program on physical functioning, as well as the concern about and fear of falling.

## Methods

### Study Design

This randomized, **open-labelled**, controlled trial included patients referred by their general practitioner to a balneotherapy center for invalidating rheumatologic conditions or venous insufficiency (ie with muscle and/or joint discomfort during mobilization sufficiently invalidating to reduce physical functioning) and screened for risk of falling at the beginning of the balneotherapy program. Participants were randomly assigned into two arms with a ratio of 1:1: (i) a 3-week balneotherapy program, either alone (control group) or associated with a physical activity and educational program during the stay at the balneotherapy center, and (ii) a one-year educational program (intervention group) (ClinicalTrials.gov number NCT03622554). The primary end point was the one-year falls incidence in both groups. The comparison of physical functioning, fear of falling, and body mass index (BMI) between the two groups after the 3-week program presented in the present paper was among the secondary end points of the main study. The inclusion period lasted for one month and was repeated four times over 2018 and 2019. The study was approved by the *Comité de Protection des Personnes Sud Méditerranée* (Committee for the Protection of Persons) (2018-A01122-53). The study complies with the Declaration of Helsinki.

### Setting

Three balneotherapy centers in the French Occitanie region (Balaruc-les-Bains, Bagnères de Bigorre, Amélie-les Bains) participated in the study.

## Participants and Randomization

### Inclusion criteria

Inclusion criteria for patients entering the study were as follows: *i*) Patients aged 65 years or older with at least one chronic disease sufficiently invalidating to justify the prescription of a balneotherapy program by their Medical Doctor *ii*) having had at least one fall in the previous year, *iii*) having a balance, muscle strength, or walking impairment defined by a maximal one-foot stance lower than 5 seconds on the dominant leg with eyes open,<sup>11</sup> or a timed up and go test,<sup>12</sup> or a five chair rising test<sup>13</sup> performed in more than 12 sec, or a walking speed < 1 meter per second.<sup>14</sup>

### Trial Procedures and Intervention

As for all patients entering a balneotherapy center in France, they needed to have had a physical examination by a Medical Doctor to ensure the absence of contraindications to the balneotherapy program. Contraindications included a significant impairment in mental or health status, and signs of acute heart or respiratory failure sufficiently severe to make the balneotherapy inadapted or dangerous. All patients entering one of the three balneotherapy centers participating in the study were informed of the objectives of the study and the required inclusion criteria.

After signing a first informed consent to check the inclusion criteria, all participants wishing to enter the study provided a second written informed consent and completed baseline testing. They were randomly assigned by the Center of clinical investigation of our hospital with equal probability to the intervention group or control group by a centralized Web-based system (Ennov-Clinical software). Randomization was performed by minimization and stratified according to the center, sex, and age (65–75; 75 and more).

## The Balneotherapy Program

Even if delivered by different care providers, the 3-week balneotherapy program was identical in each of the 3 centers. It included one and a half to two hours of care per day with (i) thermal water or mud, (ii) showers, (iii) baths with water jets, (iv) massages and (v) active mobilization in the thermal swimming pool. The common objectives of the balneotherapy program proposed in both groups of patients were to stimulate and relax muscles, improve joint flexibility, venous return, and mobility as well as to reduce joint and muscle pain.

## The Intervention Program

In the intervention group, the 3-week balneotherapy program was combined with an Adapted Physical Activities-Health Education (APA-HE) program, and a Therapeutic Patient Education (TPE) program. Even if delivered by different care providers, the APA-HE and TPE programs were identical in the 3 balneotherapy centers.

The 3-week APA-HE program is adapted from the PBM-HE program. It is characterized by an adaptation of exercises to the group's profile (an individualization of instructions, exercises according to the functions to be mobilized, a progressiveness over the sessions in terms of intensity/difficulty as well as an alternation between two forms of work to promote progress: exercises aimed at improving postural function and balance and exercises aimed at improving joint and muscle function)<sup>15</sup> (see [Online Supplement 1](#)). The APA-HE program included 12 physical activity sessions (4 sessions per week) of 60 minutes per session (45 minutes of exercise and 15 minutes of health education focusing on non-medical measures able to improve health status, including physical activity, nutrition and, especially, measures to improve sleeping).

The Therapeutic Patient Education (TPE) program consisted of three 90-minute sessions whose objectives were to allow participants to develop the following competencies: 1. safety skills: daily living gestures, footwear, managing medication and alcohol consumption, ability to get up from the ground on one's own; 2. self-care skills: recognizing falls risk factors, engaging in physical activity, home safety, balanced diet, eyesight check; 3. psycho-social adaptation skills: regaining self-confidence after a fall, using local aids, knowing how to alert in the event of a fall. The themes of the group workshops were "Experiencing a fall", "Managing balance and fall prevention factors", and "Lifestyle habits: balancing your diet, limiting alcoholic beverages, managing your daily treatment".

## Outcomes of the Present Study

All of the following outcomes were measured at the beginning (baseline) and at the end of the 3-week stay in the balneotherapy center. They were measured in both groups and by the same assessor who was unaware of patient allocation (see [Online Supplement 2](#) for more details).

- The maximum one-foot stance time on the dominant leg with eyes open.<sup>11</sup>
- The time to perform the timed up and go test.<sup>12</sup>
- The maximum grip strength.<sup>16</sup>
- The Short Physical Performance Battery score (SPPB).<sup>17</sup>
- The Falls Efficacy Scale.<sup>18</sup>
- The fear of falling, measured using a Visual Analog Scale.<sup>19</sup>
- The body mass index (Body weight/[body height]<sup>2</sup>).

## Number of Patients to Be Studied

In a preliminary study conducted in 1741 patients referred to the Balaruc-les-Bains balneotherapy center, the annual incidence of falls was 34 per 100 patients aged 65 and over.<sup>10</sup> Based on previous studies that assessed the effectiveness of physical exercise<sup>20</sup> or educational programs<sup>21</sup> in patients at risk of falling, our hypothesis was that the one-year program (the 3-week balneotherapy program combined with an Adapted Physical Activities-Health Education (APA-HE) program, and a one-year Therapeutic Patient Education (TPE)) may reduce the one-year incidence of falls by 30%. Considering a power of 90% and an alpha risk of 5%, the number of patients to include in the study to assess this hypothesis was of 112 in each group. As the rate of lost to follow-up was estimated at around 15%, 130 patients were included in each group. Only patients who completed the one-year follow-up study were included in the present analysis.

## Statistical methods

Two analysis sets were defined: (i) the Randomized Set (RS), including all patients who signed an informed consent form, and (ii) the Intention To Treat modified (ITTm), including randomized patients who had a measurement of outcomes at the beginning and at the end of the 3-week program. The present study shows results using the ITTm. Baseline characteristics of patients in the control and intervention groups are described using frequency and proportions for categorical variables and median with interquartile range [First quartile (Q1); third quartile (Q3)] or mean (SD) for continuous variables. The variation of parameters between baseline and the end of the 3-week program was assessed in each group using non-parametric paired Wilcoxon test. The variation of the parameters between baseline and the end of the 3-week program was compared between the two groups using the non-parametric Mann–Whitney test. The effect size with the Cohen's d was reported. A value of lower than 0.2 indicates the lack of clinically significant effect. A value of 0.2 represents a small effect size, a value of 0.5 a medium effect size, and a value of 0.8 a large effect size.

Longitudinal analyses were also performed using the linear mixed model (LMM) that modeled the change in each continuous outcome over time. This model combined (i) fixed effects: a group effect (intervention and control), a time effect (baseline and 3-week) and a group-by-time interaction effect, and (ii) a random effect: a random intercept which takes into account the correlation between the different observations for a same patient. The model was adjusted on the stratification variables (age, center, and gender).

All tests were two-sided tests and p-values < 0.05 were considered as statistically significant. All statistical analyses were performed with the SAS 9.4 (SAS Institute, Cary, NC, USA) software and R version 4.3.1.

## Results

### Characteristics of the Study Participants

Over the inclusion period, 13,010 subjects aged over 65 years entered the 3 centers involved in the study. Around 15% of these participants were eligible to enter the study. Among eligible patients, 253 (12.5%) accepted to participate in the study and were randomized (control group = 127; intervention group = 126) ([Figure 1](#)). In the control group, 100, 19, and 8 patients were included in the Balaruc-les-Bains, Bagnères, and Amélie-les-Bains centers and 96, 20, and 10 in the

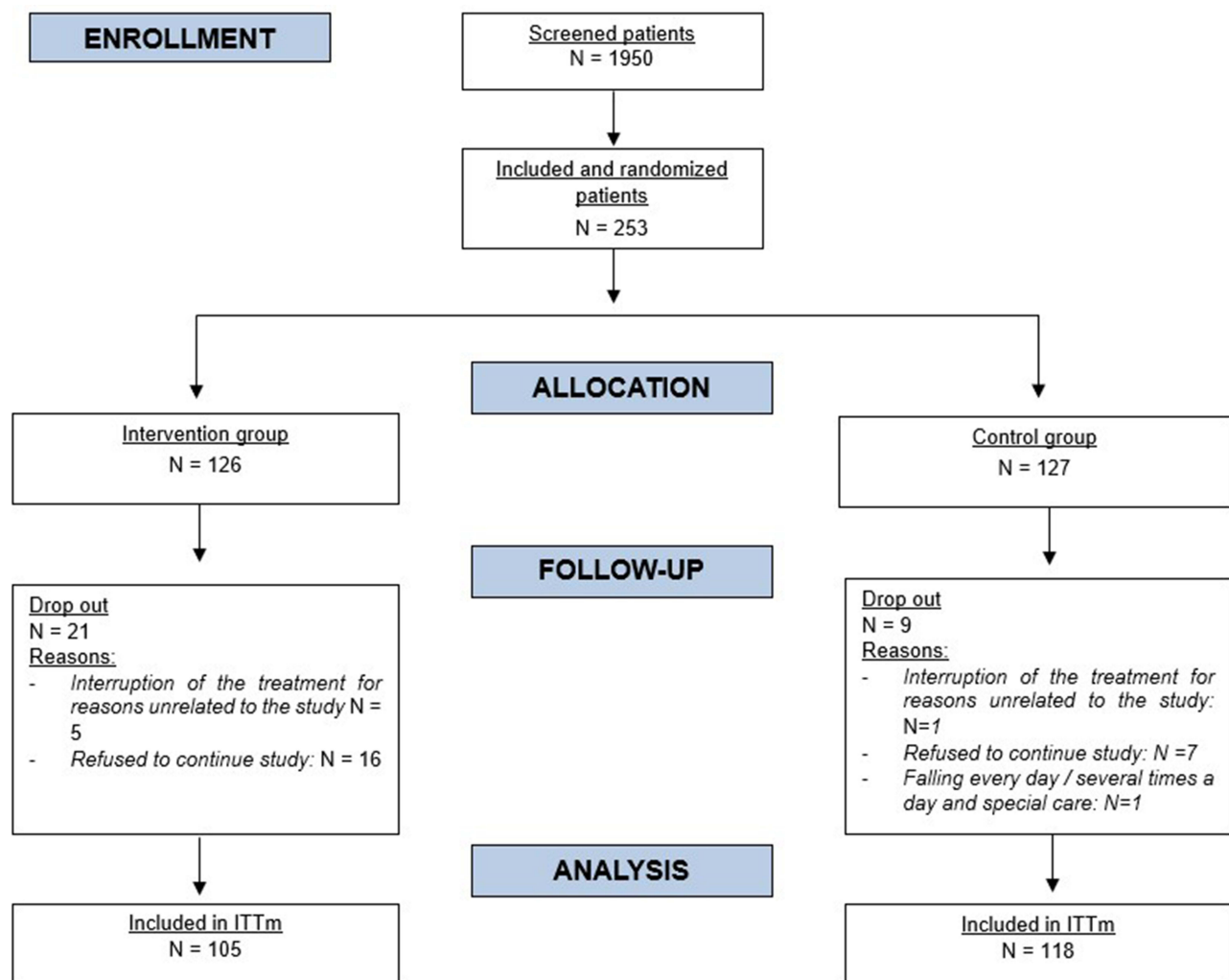


Figure 1 Flow Diagram.

intervention group, respectively. The main characteristics of patients included in both groups are displayed in Table 1. More than two-thirds of the patients included in the study were admitted for invalidating osteoarthritis.

### Effects of the 3-Week Program in the Control and Intervention Groups (Table 1)

In the control group, the 3-week balneotherapy program increased grip strength (Cohen's  $d = 0.34$  [0.17–0.53];  $p = 0.0002$ ). It also significantly decreased the time taken to perform the five chair rising test ( $d = 0.48$  [0.33–0.64],  $p = 0.0001$ ). The 3-week balneotherapy program improved physical performance assessed by the Short Physical Performance Battery ( $d = 0.40$  [0.21–0.58],  $p = 0.00001$ ) but had no significant clinical effect neither on the timed up and go test ( $d = 0.11$  [0.05–0.41];  $p = 0.0036$ ) nor on the time stance on one foot with eyes open test ( $d = 0.18$  [0.02–0.36],  $p = 0.053$ ). The balneotherapy program substantially increased the concern about falling (assessed by the falls efficacy scale [ $d = 0.27$  [0.08–0.46];  $p = 0.006$ ]) and tended to also increase the fear of falling [ $d = 0.21$  [0.05–0.37],  $p = 0.08$ ]. The program had no effect on body mass.

In the intervention group, the program had a clinical effect on all functional parameters (one-foot stance, timed up and go, five chair rising, grip strength, 4-meter walking, the Short physical performance battery), with Cohen's  $d$  between 0.37 and 0.84. It also significantly reduced the concern about falling (assessed by the falls efficacy scale ( $d = 0.49$  [0.97–0.73],  $p = 0.00001$ )) and the BMI ( $d = 0.26$  [0.08–0.42],  $p = 0.0027$ ).

**Table 1** Effects at 3 weeks of a Balneotherapy Program Alone (Control Group) or Combined with a 3-Week Physical Activity and Educational Program (Intervention Group) on Physical Parameters, Body Mass Index, and Concern About / Fear of Falling

| Variables   | Control Group (n=118) |                           |               |                                | Intervention Group (n=105) |                           |                                |               |
|---|-----------------------|---------------------------|---------------|--------------------------------|----------------------------|---------------------------|--------------------------------|---------------|
|   | Baseline              | End of the 3-week program | P intra-group | Effect size (CI 95%) Cohen's d | Baseline                   | End of the 3-week program | Effect size (CI 95%) Cohen's d | P intra-group |
| Women (%)   | 80.5                  |                           |               |                                | 89.5                       |                           |                                |               |
| Alone at home (%)   | 43.2                  |                           |               |                                | 43.8                       |                           |                                |               |
| Osteoarthritis (%)  | 63.6                  |                           |               |                                | 63.8                       |                           |                                |               |
| Falls: number in the last year.                                     | 3 (2;5)               |                           |               |                                | 2 (1;6)                    |                           |                                |               |
| Median (Q1-Q3)  |                       |                           |               |                                |                            |                           |                                |               |
| Number of falls with minor injuries in the last year Median (Q1-Q3) | 1 (0;2)               |                           |               |                                | 1 (0;2)                    |                           |                                |               |
| Maximum one-foot stance time eyes open in seconds Mean (SD)         | 6.44 (3.40)           | 7.05 (3.30)               | 0.053         | 0.18 [0.02–0.364]              | 6.75 (3.54)                | 8.52 (2.72)               | 0.58 [0.40–0.75]               | 0.00001       |
| Timed up and go test in seconds. Mean (SD)                          | 13.11 (3.83)          | 12.59 (3.61)              | 0.0027        | 0.11 [0.06–0.43]               | 13.26 (3.23)               | 11.16 (2.53)              | 0.86 [0.68–1.09]               | 0.00001       |
| Five chair rising test in seconds Mean (SD)                         | 17.29 (6.36)          | 14.92 (4.06)              | 0.0001        | 0.46 [0.32–0.63]               | 16.69 (6.45)               | 13.28 (3.82)              | 0.72 [0.57–0.92]               | 0.00001       |
| 4-meter walk test in seconds Mean (SD)                              | 5.10 (1.44)           | 4.73 (1.30)               | 0.0023        | 0.29 (0.12–0.45]               | 4.88 (1.06)                | 4.30 (0.78)               | 0.49 [0.33–0.64]               | 0.00001       |
| Grip strength (kg) Mean (SD)  | 20.88 (7.77)          | 22.32 (8.28)              | 0.0003        | 0.33 [0.16–0.52]               | 20.76 (6.75)               | 22.37 (7.84)              | 0.36 [0.19–0.55]               | 0.0008        |
| Short physical performance battery score. Mean (SD)                 | 8.90 (1.88)           | 9.52 (1.86)               | 0.00001       | 0.43 [0.26–0.64]               | 9.01 (1.7)                 | 10.22 (1.5)               | 0.83 [0.64–1.0]                | 0.00001       |
| Body Mass index (kg/m <sup>2</sup> ) Mean (SD)                      | 26.08 (3.99)          | 26.14 (3.81)              | 0.95          | 0.05 [0.17–0.18]               | 27.26 (4.23)               | 27.08 (4.13)              | 0.26 [0.07–0.44]               | 0.0027        |
| Falls Efficacy Scale Mean (SD)                                      | 28.61 (8.54)          | 27.25 (7.87)              | 0.008         | 0.27 [0.09–0.47]               | 28.65 (7.53)               | 26.01 (6.36)              | 0.49 [0.27–0.73]               | 0.00001       |
| Fear of falling (visual analog score/10). Mean (SD)                 | 4.63 (2.70)           | 5.14 (2.70)               | 0.06          | 0.22 [0.05–0.37]               | 4.91 (2.59)                | 4.47 (2.73)               | 0.14 [0.06–0.37]               | 0.04          |



## Comparison of the Effects of the 3-Week Program Between the Control and Intervention Groups (Table 2)

When compared to the 3-week balneotherapy program alone, adding a combined physical activity and educational program significantly improved (i) the balance on one foot with eyes open ( $d = 0.38$  [0.09–0.65],  $p = 0.02$ ), (ii) the performance of patients to perform the timed up and go test ( $d = -0.44$  [–0.67 to –0.23],  $p = 0.005$ ), and (iii) the physical performance battery (0.43 [0.16–0.70],  $p = 0.005$ ). However, it did not improve the 4-meter walk test or the grip strength. It reduced significantly the concern about falling (assessed by the Falls Efficacy Scale score ( $d = -0.25$  (–0.54 to 0.04],  $p = 0.03$ )), the fear of falling ( $-0.33$  [–0.63 to –0.05],  $p = 0.005$ ), and the BMI ( $d = -0.21$  (–0.40–0.03),  $p = 0.04$ ).

## Effects of the Balneotherapy Program Using a Linear Mixed Model (Table 3)

There are no significant differences for any parameters between groups except for body mass index ( $p = 0.008$ ). The time effect is significant for all parameters except for the timed up and go test and the BMI. The variation between groups (interaction time\*group effect) is significant in (i) the one-foot stance time hold eyes open (significantly increased in the intervention group), (ii) the time to perform the timed up and go test (significantly decreased in the intervention group), (iii) the Short physical performance battery score (significantly increased in the intervention group), and (iv) the fear of falling (significantly decreased in the intervention group). The falls efficacy scale score is close to significance.

## Discussion

The two main results of the present study are as follows:

i) A 3-week standard balneotherapy program indicated for rheumatologic conditions or venous insufficiency in patients screened for risk of falling at the entrance of the balneotherapy center improves (a) leg and grip strength, (b) walking speed and, more globally, (c) physical performance (Short Physical Performance battery).

However, it does not significantly improve balance, assessed by the timed up and go test and the time stance on one foot with eyes open test. The program can even increase the concern about and fear of falling and has no effect on the body mass.

ii) Adding a specific fall prevention physical activity and educational program to the standard balneotherapy schedule is extremely beneficial. Dedicated to preventing falls, this additional program further improves physical functioning (assessed by the SPPB) as well as balance (clinically positive effects on one-foot stance time with eyes open and timed

**Table 2** Comparison of the Effects at 3 weeks on Physical Parameters, Body Mass Index, and Concern About / Fear of Falling of a Balneotherapy Program Alone (Control Group) Vs a Balneotherapy Program Combined with a Physical Activity and Educational Program (Intervention Group)

| Variables  | N*  | Control Group<br>(n=118) | N*  | Intervention Group<br>(n=105) | Effect Size<br>(CI 95%)<br>Cohen's d | P-value |
|--|-----|--------------------------|-----|-------------------------------|--------------------------------------|---------|
| One-foot stance time Eyes open in seconds. Mean (SD) | 118 | 0.61 (3.32)              | 103 | 1.77 (3.0)                    | 0.36 [0.12; 0.61]                    | 0.03    |
| Timed up and go test in seconds. Mean (SD)           | 118 | –0.52 (4.50)             | 104 | –2.10 (2.45)                  | –0.44 [–0.66;0.23]                   | 0.005   |
| Five chair rising test in seconds. Mean (SD)         | 115 | –2.37 (5.09)             | 102 | –3.41 (4.72)                  | –0.21 [–0.5;0.06]                    | 0.05    |
| Four meters walking in seconds. Mean (SD)            | 118 | –0.37 (1.27)             | 104 | –0.58 (1.19)                  | –0.17 [–0.46;0.07]                   | 0.16    |
| Grip strength (kg) Mean (SD)                         | 118 | 1.44 (4.39)              | 104 | 1.61 4.42)                    | 0.04 [–0.25;0.29]                    | 0.9     |
| Short physical performance battery score. Mean (SD)  | 118 | 0.62 (1.43)              | 104 | 1.21 (1.47)                   | 0.41 [0.15;0.67]                     | 0.0005  |
| Body mass index (kg/m <sup>2</sup> ). Mean (SD)      | 118 | 0.06 (1.3)               | 100 | –0.18 (0.70)                  | –0.23 [–0.44;0.005]                  | 0.03    |
| Falls Efficacy Scale score. Mean (SD)                | 108 | –1.36 (5.04)             | 92  | –2.64 (5.44)                  | –0.24 [–0.52;0.02]                   | 0.04    |
| Fear of falling (visual analog score/10). Mean (SD)  | 114 | 0.50 (2.29)              | 103 | –0.44 (3.14)                  | –0.34 [–0.64;0.06]                   | 0.005   |

**Note:** \* N is the number patients with data at baseline and at the end of the 3-week program, for each parameter.

**Abbreviation:** SD, Standard deviation.

**Table 3** Results of the Linear Mixed Models Adjusted on the Stratification Variables (Age, Center and Gender)

| Variables                                 | Group effect |       |         | Time effect |       |         | Interaction Group*Time effect |       |         |
|---|--------------|-------|---------|-------------|-------|---------|-------------------------------|-------|---------|
|   | Estimate     | SD    | P-value | Estimate    | SD    | P-value | Estimate                      | SD    | P-value |
| One-foot stance time Eyes open in seconds | 0.117        | 0.432 | 0.788   | 0.612       | 0.295 | 0.039   | 1.194                         | 0.431 | 0.006   |
| Timed up and go test in seconds           | 0.309        | 0.441 | 0.484   | -0.518      | 0.340 | 0.129   | -1.611                        | 0.496 | 0.001   |
| Five chair rising test in seconds         | -0.823       | 0.704 | 0.243   | -2.423      | 0.460 | <0.001  | -0.962                        | 0.670 | 0.153   |
| Four meters walking in seconds            | -0.187       | 0.157 | 0.234   | -0.370      | 0.114 | 0.001   | -0.219                        | 0.166 | 0.189   |
| Grip strength (kg)                        | 0.833        | 0.814 | 0.307   | 1.445       | 0.405 | <0.001  | 0.158                         | 0.592 | 0.790   |
| Short physical performance battery score  | 0.106        | 0.228 | 0.643   | 0.619       | 0.133 | <0.001  | 0.593                         | 0.195 | 0.003   |
| Body mass index (kg/m <sup>2</sup> )      | 1.423        | 0.535 | 0.008   | 0.061       | 0.099 | 0.539   | -0.246                        | 0.146 | 0.093   |
| Falls Efficacy Scale score                | -0.299       | 1.053 | 0.776   | -1.322      | 0.501 | 0.009   | -1.302                        | 0.737 | 0.080   |
| Fear of falling (visual analog score/10)  | 0.112        | 0.349 | 0.748   | 0.506       | 0.253 | 0.047   | -0.946                        | 0.369 | 0.011   |

up and go test). It also reduces the patients' concern about/fear of falling and tends to reduce body weight (trend to BMI decrease).

Several studies and reviews concluded recently that balneotherapy, associated or not to mud therapy, is effective on a short-term basis in reducing pain and improving stiffness and quality of life in osteoarthritis patients.<sup>22</sup> The effect of balneotherapy on pain and joint stiffness could partly explain why the 3-week balneotherapy program tested in the present study is associated with a significant improvement of physical functioning, assessed by the short physical performance battery.

Whether balneotherapy programs may improve patients' balance is unclear. Two studies showed some stabilometric improvements in patients with high fat mass<sup>23</sup> or knee osteoarthritis<sup>24</sup> whereas one did not find any postural benefit in patients with different conditions.<sup>25</sup> The originality of our study is that we included only patients at risk of falling (ie with a history of fall in the previous year and with significant gait or balance disturbances).<sup>6</sup> These patients may represent more than one-third of those referred to balneotherapy programs.<sup>10</sup> We found that the balneotherapy program was able to improve global functioning but not balance (assessed by the maximum one leg stance eyes open test and the timed up and go test).<sup>6</sup> It is possible that the lack of positive impact of balneotherapy on balance may be due to insufficient proprioceptive input during massages and neuromuscular mobilization in water.

The effects of balneotherapy on muscle strength are also to be clarified. One study conducted in 10 obese patients with knee osteoarthritis showed that hydrokinesitherapy in a thermal environment was able to promote pain relief, and improve joint function and walking speed, but that it did not improve muscle strength.<sup>26</sup> Another study conducted in 56 patients with bilateral hand osteoarthritis showed that paraffin bath therapy (5 times per week for a 3-week duration) may improve hand-grip strength and the left lateral and chuck pinch strength.<sup>27</sup> In patients with a referral to balneotherapy due to a sufficiently invalidating health status (having induced a recent fall and an impaired physical functioning – notably invalidating osteoarthritis), the present study shows that a 3-week balneotherapy program may improve muscle strength of the upper (grip strength) and lower (five chair rising test) limbs. In patients referred due to conditions sufficiently invalidating to indicate a balneotherapy program and to induce a recent fall and an impaired physical functioning (essentially invalidating osteoarthritis), the present study shows that a 3-week balneotherapy program may improve muscle strength of the upper (grip strength) and lower (five chair rising test) limbs. The possible mechanisms of the positive effect of balneotherapy on muscle strength may be linked to reduced pain and increased joint mobility, as for the study conducted in hand osteoarthritis patients.

Another result of the study is that adding a physical activity and educational program to the standard balneotherapy program further improves the positive effects on physical functioning and, above all, balance. This underlines the interest of screening patients for risk of falling upon admission to the balneotherapy center and proposing the supplementary specific exercises and education recommended for those at risk of falling.<sup>6</sup>



One unexpected result is the increase in the concern about/fear of falling after the 3-week balneotherapy program, despite the significant improvement of most of the functional parameters known to be associated with a reduced risk of falling. This increased concern about and fear of falling could be due to the improved mobility made possible by the balneotherapy program, but without balance improvement. The association between physical activity and fear of falling has indeed been observed in older people with long-term disability.<sup>28</sup>

Interestingly, concerns about and fear of falling were decreased in the patients for whom the balneotherapy program was completed by specific exercises to improve balance and by an educational program. The educational program may have had a specific effect on the concern about and fear of falling since balneotherapy centers are settings with a high risk of falls and fall-related injuries<sup>29</sup> due to, for example, their wet grounds.

The last result of the study is that the balneotherapy program can lead to weight loss only when associated with a physical activity and an educational program. Physical activity itself – by the increase in mobility of patients but also by the educational program providing information on appropriate nutrition – may be an explanation of this result. Recent studies showed a U-shape relationship between BMI and falls risk. In the present study, most patients were females, with a mean BMI of 26–27 kg/m<sup>2</sup>. In community-dwelling older adults with obesity associated with invalidating conditions such as osteoarthritis, the reduction of BMI most probably has a clinical effect on the risk of falling.<sup>30</sup>

The strengths of this study are the randomized-controlled design, the homogeneous characteristics of patients selected on their risk of falling and the use of outcomes considered as reliable and strong predictors of incidence of falls.

The first limit of the study is that the paper displays intermediate results (after the 3-week program) of a study designed to test the effects on falls incidence of a combined intervention: physical activity and educational program during the stay at the balneotherapy center to improve awareness of the benefits of physical activity programs associated with a one-year fall prevention educational program. However, the analysis of this secondary outcome was planned in the protocol submitted to the AFRETH that funded the study and to the Committee for the Protection of Persons. The short interval between the assessments of physical parameters (3weeks) may have induced a learning effect in patients that could have overestimated the benefits of the balneotherapy program on the physical functioning. However, a potential learning effect probably had only a minor effect on the comparison of the control and the intervention groups, ie on the benefits on balance of the fall prevention physical activity and educational program. Another limit is that the majority of patients entering the balneotherapy centers were females and had invalidating osteoarthritis. Extrapolating our results to patients with other characteristics is not possible. The number of patients leaving the program was higher in the intervention group. However, none of the patients left the study due to adverse effects of the exercise / educational program.

## Conclusions

Our results show that a usual 3-week balneotherapy program improves the strength in the upper and lower limbs as well as the walking speed, but does not improve the balance in patients with chronic diseases sufficiently invalidating or painful to induce falls. Adding a specific exercise and educational program aimed at reducing the risk of falls improves balance significantly (assessed by the one-foot stance time eyes open and the timed up and go test) and reduces the concern about/fear of falling. These results suggest the interest of assessing the risk of falls in older patients referred by their general practitioner to a balneotherapy program. Patients at risk of falling should be offered, in addition to the balneotherapy program (that increases their muscle strength and walking speed) specific fall prevention exercises as well as an educational program aimed at improving their balance and reducing their concern about/fear of falling. It would be valuable to determine whether continuing the educational program aimed at preventing falls in the year following the intervention reduces the incidence of falls in these patients aware of the benefits of a 3-week fall prevention and educational program.

## Registration and Protocol

This analysis has been registered in ClinicalTrials.gov number NCT03622554.

## Data Sharing Statement

Data are available on request from the corresponding author.

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## Author Contributions

All authors made a significant contribution to the work reported, whether in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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