Clinical Interventions in Aging

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CLINICAL TRIAL REPORT

Influence of Coaching on Effectiveness, Participation, and Safety of an Exercise Program for Postmenopausal Women with Osteoporosis: A Randomized Trial

Laura Bragonzoni[1], Giuseppe Barone[1], Francesco Benvenuti[1], Claudio Ripamonti[2], Lucia Lisi[2], Maria Grazia Benedetti[3], Sofia Marini[1], Laura Dallolio[4], Pasqualino Maietta Latessa[1], Raffaele Zinno[1], Giuseppe Audino[1], Wolfgang Kemmler[5], Erika Pinelli[1]

[1]Department for Life Quality Studies, Campus of Rimini, University of Bologna, Bologna, Rimini, Italy; [2]Center for Osteoporosis and Bone Metabolic Disease, IRCCS Rizzoli Orthopaedic Institute, Bologna, Italy; [3]Physical Medicine and Rehabilitation Unit, IRCCS Rizzoli Orthopaedic Institute, Bologna, Italy; [4]Department of Biomedical and Neuromotor Sciences, University of Bologna, Bologna, Italy; [5]Institute of Medical Physics, Friedrich-Alexander-University Erlangen-Nürnberg, Erlangen, Germany

Correspondence: Giuseppe Barone, Department for Life Quality Studies, Campus of Rimini, University of Bologna, Via di Barbiano, 1/10, Bologna, Rimini, 40136, Italy, Tel +39 051 636 6507, Email giuseppe.barone8@unibo.it

Purpose: We compared two different strategies providing professional coaching to administer an exercise program for women with postmenopausal osteoporosis (POP): individual training (IT) at home with trainer's supervision provided by telephone contacts at regular time-intervals or group training (GT) with trainer's live supervision. Our working hypothesis was that IT is a valid alternative to GT when GT is not feasible.

Patients and Methods: This was a single-blind, randomized study. We recruited 52 women with POP, without significant comorbidity, and no participation in any structured exercise program within the previous 6 months. They were assigned randomly to IT or GT groups (n = 26 each). Distribution of age (IT: 68±4, GT: 67±8 years) and body mass index (IT: 23.0±2.5, GT: 21.4±5.1) was similar between groups. Each group performed the exercise program in two 1-hour sessions per week for 18 months. Primary outcome measure was Health-Related Quality of Life (HRQoL), as measured by the Short Osteoporosis Quality of Life Questionnaire. Secondary outcome measures focused on domains acknowledged to influence HRQoL (disability, fear of falling, weekly physical activity, physical function) or the effectiveness of the exercise program (retention, adherence, and safety). Significance level was set at $p < 0.05$.

Results: No significant differences were observed between IT and GT groups for any domain. Retention, adherence, and safety were also similar. HRQoL, disability and fear of falling did not change between baseline and follow-up for either group. However, for both groups, physical function (knee flexion, shoulder mobility) and functional capacity (6-minute walking test) improved. Weekly physical activity levels increased from moderate range at baseline to intense at final assessment for both groups.

Conclusion: IT and GT supervised exercise programs for women with POP provide similar effectiveness, participation and safety. Hence, both modalities should be considered for future translation in clinical practice of exercise recommendations for POP.

Keywords: coaching, encouragement, exercise, physical activity, postmenopausal osteoporosis, quality of life

Introduction

Physical activity is effective in the prevention of postmenopausal osteoporosis (POP) and its consequences.[1,2] Several studies consistently proved the efficacy of exercise programs versus no exercise, sham programs, or pharmacological therapy in women with POP[3–6] in which coaching and encouragement was provided either by telephone remote contacts in home individual training (IT), or by trainer's live supervision in group training (GT). However, no study has compared

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the effects of an exercise program specifically designed for women with POP in which coaching and encouragement were provided with or without live supervision.

Coaching and encouragement are of paramount importance to promote exercise efficacy and adherence.[7] A few studies designed for the prevention of other conditions compared the benefits of exercise programs in which coaching and encouragement were provided with or without supervision. Two studies observed that exercise aimed at improving pain and function in chronic nonspecific low back pain is more effective when delivered in gyms with live supervision.[8,9] Other studies compared the Otago exercise programs for fall prevention and demonstrated better outcomes with supervision[10,11] for variables related to physical and mental health with supervision.[10,11]

Differences in terms of supervision may influence the adherence to the exercise program between the two groups which may have different impact on the outcome measures. On the other hand, IT could be a valid alternative to GT since, from the theoretical point of view, it could overcome problems related to accessibility to gyms or time-schedule rigidity. The rationale and protocol details of our study have been previously published.[12]

With the goal of providing evidence for future translation of an exercise program for women with POP into clinical practice and recommendations, we compared IT and GT strategies to provide coaching and encouragement. The exercise program[13] was based on the most recent scientific evidence in this field.[14–16] Our working hypothesis was that the effectiveness on health-related quality of life (HRQoL), physical function, participation, and safety of the exercise program are the same when coaching and encouragement are provided by live supervision as for the GT or by telephone contacts at regular time intervals such as IT.

Materials and Methods

This study was carried out within the project "Physical ACTivity: the tool to improve the quality of LIFE in osteoporosis people" (ACTLIFE) funded by European Commission within the Erasmus+ Sport program (Grant Agreement N2017-2128/001-001). The study was approved from the Local Ethics Committee (Comitato Etico Indipendente di Area Vasta Emilia Centro, CE-AVEC) of the Emilia-Romagna Region. The trial was registered in ClinicalTrial.Gov (NCT04179903). Amendments of the study protocol induced by the COVID-19 outbreak (see below) were also approved by these same Local Ethics Committee. All the study participants gave their written informed consent after detailed information.

This was a single-blinded randomized trial as practitioners evaluating subjects were unaware which exercise group they were assigned. Women with POP (Lumbar spine or femur T-score ≤-2.5 SD) without any significant motor or cognitive comorbidity were recruited by the Centro Osteoporosi e Malattie Metaboliche dello Scheletro of Rizzoli Orthopaedic Institute of Bologna, Italy. The original study protocol has been previously published and we refer to it for greater details on study design, inclusion and exclusion criteria, outcome measures, and exercise program.[12]

We included women with POP (lumbar spine or femur T-score ≤ −2.5), menopause age ≥40 years (to exclude women with premature ovarian failure),[17] Short Physical Performance Battery (SPPB) ≥6, under stable pharmacologic therapy, and not having followed any regular and structured exercise program in the previous 6 months. We excluded women with secondary osteoporosis, severe impairment of communicative and/or sensorial functions, heart failure (NYHA class ≥2), unstable angina, pulmonary disease requiring oxygen therapy, symptomatic orthostatic hypotension, hypertension in poor pharmacologic control (diastolic >90 mmHg, systolic >140 mmHg), previous implant of prosthesis at upper or lower limbs, relevant neurological condition impairing motor or cognitive function or any other condition that the general practitioner considered to contraindicate the participation in an exercise program of moderate intensity.

Intervention

This study compared the effectiveness of an exercise program[13] administered in two parallel groups as IT or GT. The exercise program was aimed at increasing joint mobility, muscular strength, static and dynamic balance, motor coordination, and endurance. Each group was scheduled to perform the exercise program in two 1-h sessions per week using the same simple equipment (mats, sticks, soft balls, elastic bands, and small weights 0.5–3.0 kg). Each exercise session started with 10–15 min warm up consisting of different types of walk, joint mobility, and static or dynamic balance. The balance component consisted of 4 to 5 exercises that challenged postural control in static and

dynamic conditions. Exercises were performed in monopedal and bipedal stance on different surfaces, with eyes open or closed. The warm-up was followed by a central session which included exercises of strength and impact. Strength exercises were performed in a multi-set regimen and included 2 exercises involving torso muscle groups, 2 exercises for lower limb muscle groups, 1 or 2 exercises involving smaller upper limb muscle groups and 2 exercises involving the abdominal and lumbar wall muscles. For each exercise, 2 to 3 sets of 6 to 12 repetitions were performed, with a rest interval ranging 20–120 seconds between series. Impact exercises have been incorporated as modifications of strength exercises, such as wall push up with impact and forward lunge with impact. The exercise session ended with 10 minutes cool-down and stretching.

During the first six weeks of exercise, we focused on familiarization, learning of correct movements and lifting technique, body sensation and the use of the Rate of Perceived Exertion Scale[18] (RPES, 1–10 score). Subsequently, we focused the exercise program on muscular strength and impact exercises of moderate intensity (RPES 4–5 score). Every six weeks we rescheduled suitable dosage and progression of exercise program. In addition, all participants were requested to choose an additional third day of the week to perform brisk walking, cycling, or swimming for at least 30 minutes with moderate intensity.

A professional trainer provided coaching using two different strategies in the two groups. In the IT group, the trainer explained the participants how to perform the exercise program at home in one to three face-to-face educational sessions. In addition, IT participants received educational printed material with detailed explanation on how to perform the exercises correctly. Subsequently, they were requested to exercise individually at home. Trainer's coaching was provided outside the exercise sessions by telephone contacts scheduled at regular intervals (once a week in the first two weeks and then twice a month for the following duration of the study). GT participants, instead, were coached and supervised during each exercise session. As described below in detail, the modality of coaching in latter group varied during the study due to the outbreak of COVID-19 pandemic.

Study Duration and Modifications of the Study Protocol Due to COVID-19 Pandemic

The study was designed to last 12 months with baseline, 6-month and 12-month assessments. The study started and progressed as scheduled until the outbreak of the COVID-19 pandemic which resulted in government imposed national restrictions of the movement of the population. The restrictions involved all non-essential businesses, including gym activity, causing the interruption of the exercise program of the GT, but not of the IT participants. Thus, the original protocol underwent modifications as shown in Figure 1.

The trainer's coaching and supervision during training sessions, while unchanged for the IT group, underwent significant modifications for the GT group during and after lockdown. From the beginning of the study to the outbreak of the pandemic in March 2020 trainer's coaching and supervision was provided in gym GT sessions. Subsequently during lockdown, the trainer asked the GT participants to continue to exercise, individually at home providing them the same type and frequency of coaching of the IT group. They were also provided educational material by e-mail. Finally, from October 2020 to the end of the study, as the pandemic situation (and consequently the government-imposed restrictions to gym activity) was prolonged, the supervision during the exercise sessions was provided by live video-assisted tele-coaching (Google Meet, by Google LLC). The latter decision was inspired by previous studies which indicate that live tele-coaching may be an effective way of providing supervision by allowing live contact with the trainer during the exercise sessions.[19,20]

The intermediate 6-month follow-up assessment was cancelled due to COVID-19 restrictions to access health-care facilities and postponed to 12 months when these restrictions were lifted. Finally, to allow GT activity to restart and continue its activity for an adequate time duration, we prolonged the study duration of 6 months. Thus, the final assessment was carried out at 18 months.

Study Outcomes

Primary Outcome

The primary outcome measure was HRQoL assessed by the Short Osteoporosis Quality of Life Questionnaire (ECOS-16).[21]

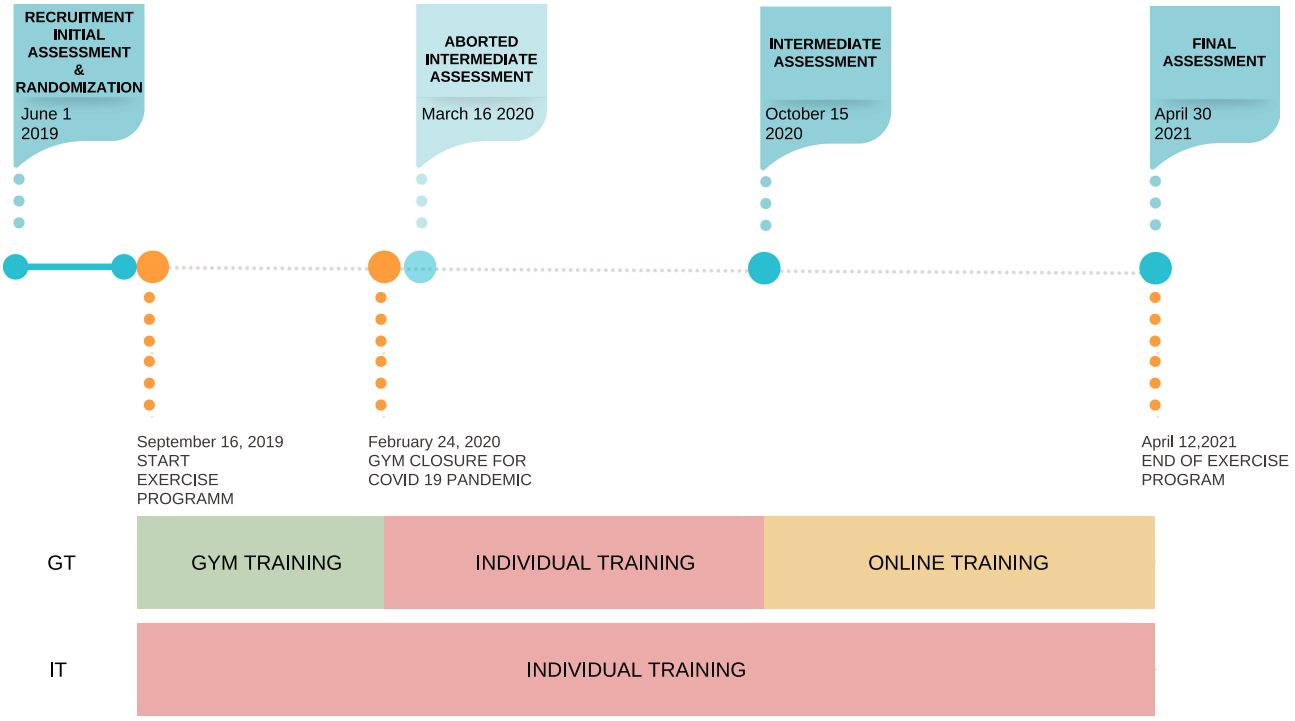

Figure 1 Study design and modifications of the study protocol caused by COVID-19 pandemic.

Secondary Outcomes

Health Related Outcomes (Questionnaires)

The outcomes measures included variables pertaining to domains recognized to influence quality of life such:

- Disability by WHO Disability Assessment Schedule, WHODAS;[22,23]
- Fear of falls by Short Falls Efficacy Scale International, Short FES-I;[24,25]
- Weekly physical activity by Physical Activity Scale for Elderly, PASE.[26–28]

Physical Function Outcomes

Physical function outcomes included measures of:

- Joint mobility was measured by the sit and reach test (extensibility of the hamstrings and lower back),[29] shoulder stick test, hip and knees by goniometry (average of the two sides);[30]
- Muscle strength by Hydraulic Hand Jamar Dynamometer®,[31] on the dominant side;
- Balance by Delos Single Stance Test®,[32] with open or closed eyes (average of the two sides);
- Functional capacity by the 6-minute walking test.[33]

Retention, Adherence and Safety

Retention in the study exercise program was estimated by the rate of participants who completed the study versus those who abandoned. Participants' adherence to the exercise program was recorded by monthly logs and estimated as attendance rate [(exercise sessions actually performed/maximum number of exercise sessions)*100]. The safety of the exercise program was evaluated by recording all adverse clinical event occurred during and outside the exercise sessions by monthly logs. In particular, falls occurred during the 3-month period before each assessment were recorded by an ad hoc questionnaire.

Finally, at the baseline, we recorded age, age of menopause, education, family and occupational status, body mass index, and femoral and vertebral bone mineral density (T-score). Outcome measures, focused on HRQoL and physical function, are summarized in Table 1.

Table 1 Outcome Measures and Time of Assessment

Domain	Instruments	Units	Assessments		
			Baseline	Intermediate Follow-Up	Final Follow-Up
Primary and secondary outcome measures					
Health Related Quality of Life	Short Osteoporosis Quality of Life Questionnaire (ECOS-16)	Score [best: 1, worst: 5]	X	X	X
Disability	WHO Disability Assessment Schedule (WHODAS)	Score [best: 0, worst: 100]	X	X	X
Fear of falling	Short Falls Efficacy Scale International (Short FES-I)	Score [low: 7–8, moderate: 9–13, high: 14–28]	X	X	X
Weekly Physical Activity	Physical Activity Scale for Elderly (PASE)	Score [inactivity: <42, poor activity: 43–105, moderate activity: 106–145, intense activity: >146]	X	X	X
Physical function measures					
Joint Mobility	Shoulders stick test	Cm	X	X	X
	Hip extension goniometry	Degrees [mean of two sides]	X	X	X
	Knee extension goniometry	Degrees [mean of two sides]	X	X	X
	Sit-and-reach test (spine and hamstrings)	Cm [mean of two sides]	X	X	X
Handgrip	Hydraulic Hand Jamar Dynamometer®	Kg [dominant arm]	X	X	X
Balance	Delos Postural Proprioceptive System® (Delos S.r.l., Torino): single stance test with eyes open or closed	Score [mean of two sides]	X		X
Functional capacity	6-Minute Walking Test (6MWT)	m	X	X	X

Sample Size

Power analysis was carried out with G*Power 3.1.9.2.[34] Sample size was estimated considering the questionnaire ECOS-16[21] as a primary outcome measure of the study. From published evidence, ECOS-16 has a standard deviation of 0.8 at final follow-up assessment and a minimal clinically important difference of 0.69. This led to an estimated effect size of 0.863. Considering an alpha error of 0.05 and a power of at least 0.8, the minimum size of the sample was estimated at 18 patients per group, for a total of 36 patients. Considering a 15% drop-out (estimated on the basis of the experience of a previous study focused on patients with OP vertebral fractures),[14] preferring to be even more conservative, we estimated an appropriate sample size of 26 patients for each group, for a total number of 52 participants.

Statistical Analysis

Data were analysed according to the intention-to-treat principle. Statistics were performed by IBM SPSS software, version 18 (Chicago, IL, USA). For both groups and for the three times of assessment, continuous parametric variables were summarized in terms of mean and standard deviation, ordinal nonparametric variables in terms of median and interquartile range (IRQ), and qualitative variables in terms of frequency. To compare the characteristics between the two groups at the baseline, the Student's *t*-test for unpaired samples was used for parametric quantitative variables, the Mann Whitney test for non-parametric variables and Chi-square test for qualitative dichotomous ones. Analysis of variance for repeated measures followed by Sidak test post-hoc comparisons for paired samples was used to compare changes between the two settings among baseline and follow-up assessments for parametric variables. To compare non-parametric variables collected at baseline, 12-month and 18 months for each group, the Friedman test followed by post-hoc

comparisons with Wilcoxon test for paired samples was used. The Mann–Whitney test has been used to compare non-parametric data between the two groups in each time evaluation. At baseline assessment, outcome measures were considered to present floor or ceiling effects when more than 20% of the participants presented values of the minimum or maximum possible score range <10% or >90%, respectively. Significance level was set at $p < 0.05$.

Results

Participants Characteristics, Retention and Adherence

Fifty-two women with POP were recruited, 26 allocated to the IT group and 26 to the GT group (Figure 2). They were all under stable pharmacologic therapy with bisphosphonates (23 in the IT and 22 in the GT group) or denosumab (1 in the IT and 2 in the GT group). In addition, they all assumed calcium supplementation with or without vitamin D or analogues. The baseline characteristics of the two groups are summarized in Table 2. Distribution of age (IT: 68±8, GT: 67±8 years) and body mass index (IT: 23±2.5, GT: 21.4±5.1) was similar between groups. Four women were underweight (BMI <18.5, IT: 2 and GT 2), 10 overweight (BMI 25–30, IT: 6 and GT 4) and 2 obese (BMI >30, IT: 1 and GT 1). The two groups did not show statistically significant differences at baseline for all variables, except for the sit-and-reach test.

At the end of the study, 33 (63%) women were retained in the study while 19 (37%) dropped out for various reasons: 6 women (3 IT and 3 GT) never started because not assigned to desired group or the gym was not easily accessible for

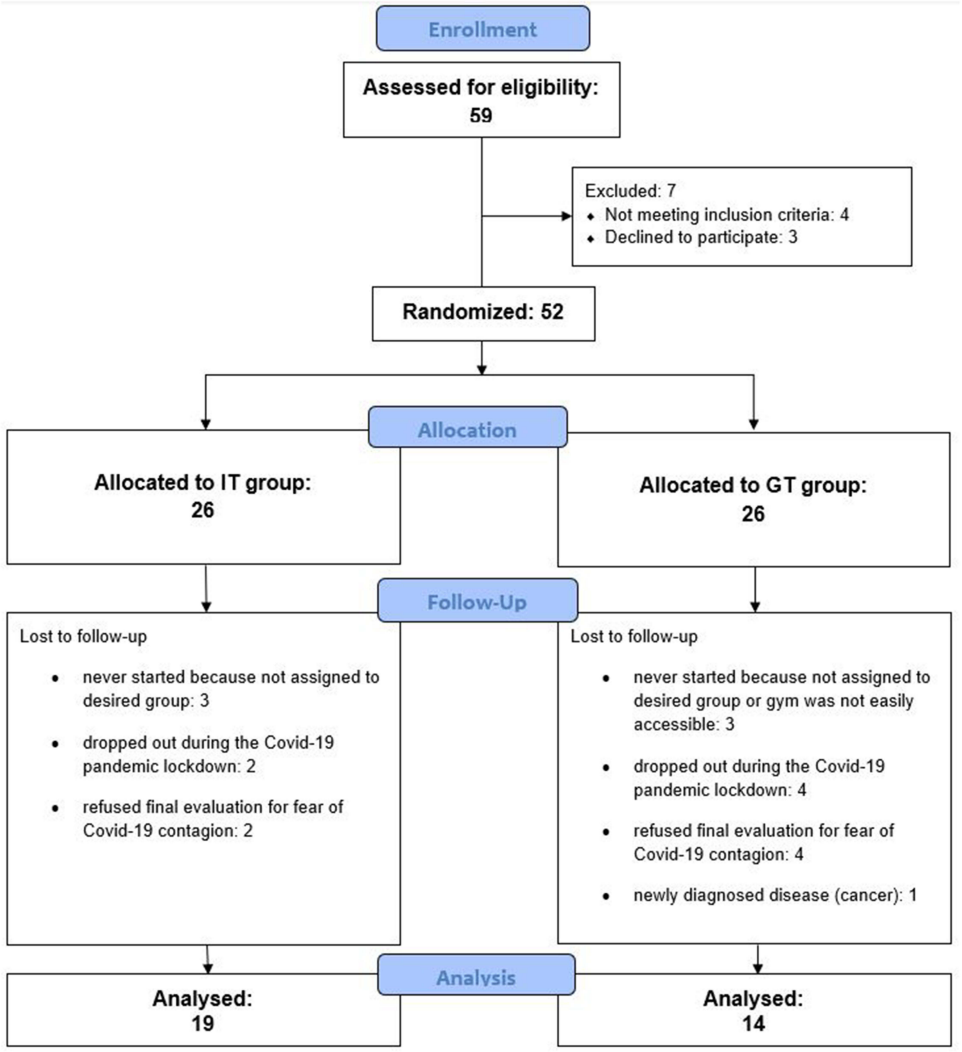

Figure 2 Consort diagram.

Table 2 Participants' Baseline Characteristics

			IT [N=26] Mean ± SD or Units	GT [N=26] Mean ± SD or Units	Statistic test	p
Demographic data	Age	Years	68.0 ± 6	67.0 ± 8	Student t	0.487
	Menopause age	Years	49.6 ± 4	50.0 ± 4	Student t	0.760
	Mineral bone density					
	Femural Neck	T-Score	−2.5 ± 0.6	−2.5 ± 0.5	Student t	0.911
	Lumbar Spine	T-Score	−2.9 ± 0.7	−3.2 ± 0.7	Student t	0.526
	Occupational Status	Retired or Unemployed	19	19	Chi-square	1.000
		Employed	7	7		
	Family Status	Single or Divorced	6	9	Chi-square	0.359
		Married	20	17		
	Education	Middle School or Lower	8	6	Chi-square	0.687
		High School Diploma or Higher	18	20		
	Weight	Kg	58.0+9	55.7+10	Student t	0.307
	Height	cm	158.1+6	157.6+5	Student t	0.423
	Body Mass Index	Kg/m^2	23.3 ± 3	21.7 ± 8	Student t	0.089
Primary and secondary outcome measures	Short Osteoporosis Quality of Life Questionnaire	Score	1.5 ± 0.5	1.8 ± 0.8	Mann Whitney	0.217
	WHO Disability Assessment Schedule	Score	29.6 ± 5	32.5 ± 8	Mann Whitney	0.140
	Short Falls Efficacy Scale International	Score	8.6 ± 2	9.3 ±3	Mann Whitney	0.361
	History of falls in the previous 3 months	Yes	7	7	Chi-square	1.000
		No	19	19		
	Physical Activity Scale for Elderly	Score	178 ± 102	177 ± 97	Mann Whitney	0.978
Physical outcome measures	Shoulders stick test	cm	29.3 ± 30	40.9 ± 37	Student t	0.147
	Hip extension goniometry	Degrees	103.4 ± 13	104.3 ± 13	Student t	0.942
	Knee extension goniometry	Degrees	126.0 ± 12	126.7 ± 9	Student t	0.184
	Sit and reach test	cm	−2.5 ± 7.5	5.6 ± 11*	Student t	0.006
	Handgrip	Kg	23.8 ± 4	21.8 ± 5	Student t	0.639
	Delos Single Stance Test, eye open	Score	85.1 ± 11	84.3 ± 10	Student t	0.934
	Delos Single Stance Test, eye closed	Score	51.3 ± 14	52.9 ± 13	Student t	0.635
	6-Minute Walking Test	m	336.0 ± 51	365.1 ± 69	Student t	0.398

them, 6 (2 IT and 4 GT) dropped out during the Covid-19 pandemic lockdown, 1 (GT) abandoned for newly diagnosed disease (cancer), and 6 (2 IT and 4 GT) refused final evaluation for fear of Covid-19 contagion. At the baseline, no statistically significant differences were observed between those who completed the study and those who dropped out for all considered variables. Finally, no differences in all baseline characteristics of the subjects of two groups (19 IT and 14 GT) who completed the study were observed.

Before the Covid-19 pandemic, median adherence rate was 87.8% (IQR 25.0) in the IT group, 83.1% (IQR 23.5) in the GT group. During the closure of the gyms due to the Covid-19 pandemic, the median adherence rate was 93.8% (IQR

Table 3 Primary and Secondary Outcomes Measures

	Groups	Median (IQR*)			Friedman Test
		Baseline Assessment	Intermediate Assessment	Final Assessment	P
Short Osteoporosis Quality of Life Questionnaire (ECOS-16)**	IT	1.7 (0.4)	1.6 (0.8)	1.6 (0.6)	0.720
	GT	1.8 (0.9)	1.8 (0.8)	1.5 (0.8)	0.199
WHO Disability Assessment Schedule (WHODAS)	IT	28.3 (4.9)	29.7 (10.9)	27.9 (5.6)	0.217
	GT	28.7 (5.8)	31.0 (8.1)	29.0 (6.1)	0.158
Short - Falls Efficacy Scale International (Short FES-I)	IT	8 (3)	8 (3)	8 (3)	0.665
	GT	8.1 (1.5)	8 (2.5)	8 (1.5)	0.944
Physical Activity Scale for Elderly (PASE)	IT	142 (90)	171.0 (105.0)	207.7 (140.0)[a]	0.006
	GT	161.55 (119.5)	200 (120.8)[a]	250 (98.3)[a]	0.001

Notes: **Ceiling effect, more than 20% participants had baseline values ≤10% of maximum possible score range. [a] $p < 0.05$ versus baseline assessment.
Abbreviation: *IQR, Interquartile Range.

21.9) in the IT group, 92.2% (IQR 32.0) in the GT group. From intermediate to final assessment, the median adherence rate was 64.6% (IQR 66.7) in the IT group, 77.1% (IQR 25.5) in the GT group. No statistically significant difference was observed between the two periods of the study and within groups (Mann–Whitney *U*-test always $P > 0.05$).

Primary and Secondary Outcome Measures

Results of primary and secondary outcome measures are summarized in Table 3. No significant differences were observed between the IT and GT groups, and between the baseline and the two follow-up assessments within each group for ECOS-16 which was the primary outcome measure of the study. However, ECOS-16 presented a ceiling effect since 37% women of the IT and 30% of the GT group scored within the <10% range of the scale (ie, self-reported good HRQoL). This result was paralleled by those of secondary outcome measures. WHODAS showed low disability levels at baseline and no statistically significant variations at the two follow-up assessments in both IT and GT groups. Both groups also presented low fear of falling as indicated by Short FES-I and no variation after the exercise program. This latter result was consistent with the observation that only a minority of studied subjects referred to have had falls in the 3 months before baseline and during the study (see below safety section). On the other hand, weekly physical activity (PASE) was in the moderate activity range (score 106–145) at baseline and increased significantly in both groups ($p < 0.0061$ for IT; $p < 0.0005$ for GT) during the study reaching the intense activity level (score >146) in both groups at the end of the study.

Physical Outcome Measures

Physical outcomes measures are summarized in Table 4. Both groups presented significant improvements of similar magnitude (always, $p < 0.0001$) of knee and shoulder mobility and functional capacity (6MWT). However, no differences

Table 4 Physical Outcome Measures

	Groups				Repeated Measures ANOVA		
		Baseline Assessment Mean ± SD	Intermediate Assessment Mean ± SD	Final Assessment Mean ± SD	Groups (G) p	Assesments (A) p	Interaction G*A p
Shoulder stick test	IT	29.3 ± 25.8	7.7 ± 11[a]	6.1 ± 10.4[a]	0.337	<0.0001	0.487
	GT	31.2 ± 35.3	19.2 ± 35.9	13.4 ± 21.7[a]			
Hip extension goniometry	IT	105.3 ± 9.9	102.4 ± 11.1	106.2 ± 7.9	0.343	0.289	0.817
	GT	109.1 ± 12.5	106.8 ± 8.7	108.5 ± 10			

(*Continued*)

Table 4 (Continued).

	Groups				Repeated Measures ANOVA		
		Baseline Assessment Mean ± SD	Intermediate Assessment Mean ± SD	Final Assessment Mean ± SD	Groups (G) p	Assesments (A) p	Interaction G*A p
Knee extension goniometry	IT	126.2 ± 13.3	126.5 ± 9.9	132.2 ± 8.9[a]	0.395	<0.0001	0.996
	GT	123.4 ± 7.9	129.3 ± 7.7	134 ± 8.4[a]			
Sit&Reach Test	IT	−2.2 ± 7.4	0.6 ± 6.5	−1.6 ± 6	0.081	0.519	0.654
	GT	3.0 ± 10.6	3.6 ± 13	1.8 ± 6			
Handgrip	IT	23.4 ± 4.4	23.5 ± 3.9	22.7 ± 4	0.840	0.996	0.339
	GT	22.9 ± 3.8	22.7 ± 3.4	23.8 ± 3.8			
Delos Single Stance Test:	IT	83.2 ± 12.4		84.8 ±8.5	0.148	0.130	0.649
Open Eyes	GT	86.8 ± 8.2		89.9 ± 2.3			
Delos Single stance Test:	IT	46.0 ± 13		48.8 ± 17.1	0.089	0.107	0.884
Closed Eyes	GT	57.3 ± 13		60.6 ± 17.4			
6-Minute Walking Test	IT	357.0 ± 57	373.3 ± 83.7	423.9 ± 72.5[a]	0.140	<0.0001	0.317
(6MWT)	GT	376.0 ± 83	422.8 ± 28.9[a]	458.1 ± 44.2[a]			

Note: [a] $p < 0.05$, post hoc tests versus baseline assessment.

were observed in the comparison between IT and GT groups. No variations were found the other joint mobility measures, muscle force and balance between follow-up and baseline assessments in both groups.

Safety

No significant adverse clinical events occurred during the study. In particular, no falls occurred during the exercise sessions in both groups. Outside the exercise sessions, 7 participants of the IT and 2 of the GT group reported one fall (chi-square test, P = 0.184) during the whole duration of the study.

Discussion

This study compared the effectiveness of an exercise program specifically designed for women with POP when administered with two different types of coaching and encouragement by a professional trainer. In the IT group participants exercised individually at home and feedback was provided by telephone calls at two-week time intervals. In the GT, participants exercised in group under the trainer's direct live supervision, which was provided first in gyms and subsequently, after the outbreak of the COVID-19 pandemic, by tele-conferencing. We found the exercise program administered as GT or IT to have similar effects in terms of adherence, safety, and on other outcome measures. Our results are consistent with previous studies which compared remote coaching and encouragement in physical activity interventions for older adults with other medical conditions and found that remote contacts in home-based programs may be a good alternative to supervised onsite exercising.[20]

Our study was focused to compare the effectiveness of different coaching and encouragement strategies in administrating the same exercise program[13] based on the most recent scientific evidence in this field.[14–16] No control group with usual care or sham exercise program was included in the study protocol because it was considered unethical to withdraw exercise from POP women when there is overwhelming evidence of the importance of exercise to maintain health to prevent falls and fractures.[3–6] However, our observations on physical function measures (joint mobility and functional capacity) and weekly physical activity are in agreement with the published evidence of the importance of the exercise program we proposed for women with POP.

Particularly relevant is the result obtained by the 6MWT, an instrument widely used to measure the impact of multiple pathological conditions on exercise capacity and function in older adults.[35] A previous study on a large sample of community dwelling older adults found that the distance travelled decreases with age, and 400 meters is the cut-off point indicating limitation of mobility and sarcopenia.[36] In our study, mean values were below this cut-off point at baseline

assessment and above it at the end of the study for both groups. At the end of the study, the walked distance increased 66.9 m (+19%) in the IT group and 82.1 m (+22%) in the GT group with respect to baseline.

The weekly physical activity measured by PASE increased in spite of all the mobility restrictions imposed by COVID-19. This may be due to the coaching and encouragement strategies adopted during the study which were not simply focused on the exercise sessions but on the promotion of a healthy active lifestyle. During lockdown, participants were encouraged to continue exercising at home by regular phone calls and any problem encountered discussed with them. The study of Barrett et al,[37] who explored the experiences of individuals who had decreased PA as a result of the COVID-19 pandemic, may support this view. They found that the individuals who decreased PA due to COVID-19 desired an autonomy-supportive counselling style, centered on listening support and self-regulatory support.

In contrast to comparable trials,[14,38] we found no improvement in the HRQoL measure (ECOS 16) which was the primary outcome measure of our study. This contradiction can be explained considering the characteristics of participants included in the present study. They all reported low scores (ie, better score) at baseline indicating that their self-assessment of HRQoL was already pretty good, thus leading to a ceiling effect. These results are consistent with those recorded for balance,[32] fear of falls,[24,25] and disability[22,23] which also indicate a very high level of physical functioning of the study population. Thus, more studies are necessary to extend the conclusions of this study to frail elderly women with POP. It is also worth noting that, although the study was conducted during COVID-19 pandemic (with consequent social restriction), we did not find any worsening of HRQoL. This is in contrast with previous studies that found deterioration of HRQoL in the aged population in association with an increased rate of mental and physical health problems associated with pandemic.[39–42] With present methods, we cannot explain this contradiction. We speculate coaching and encouragement provided the participants during the entire duration of the study, especially during the lockdown periods, may have contributed to this result.

The study was greatly affected by the outburst of Covid-19 pandemic leading to significant amendments to the original protocol[12] that may have affected the results. In particular, while coaching and encouragement were little affected by pandemic restrictions in the IT group, they changed substantially in the GT group. In the latter group the exercise program started in gyms prior to lockdown, and subsequently continued at home for the rest of study with telephone feedback and, finally, by teleconferencing since restrictions on the use of gyms were prolonged for nearly the entire duration of the study. These modifications may have diluted the differences in interventions between the two groups since direct interactions among participants in the GT group were consequently weakened or missing. Experts in group dynamics have suggested that participation in regular group activities can lead to true behaviour change through a pathway of social interaction, group bonding and behaviour imitation.[43] In other patient populations (ie, patients with cancer,[44] group exercise has been shown to result in improved quality of life, greater self-confidence, increased motivation and a sense of camaraderie with other participants).[45]

Retention and Adherence

In this study, 63.5% of subjects of both groups completed the study. This result can be rated as medium/high during the 18 months for both groups.[6] Randomisation likely impacted the abandonment of some subjects, such as workers who were part of the GT group and never started because they did not have the possibility to attend the classes during working hours, or because of the distance between the gym and their domicile. Furthermore, the lack of electronic devices and the internet, and the difficulties in using it, proved to be barriers to continue participating in the study during the lockdown. Different studies show technologies being abandoned or rejected by users due to a lack of compatibility and consumer involvement in selecting their assistive technology devices.[46,47]

Strength and Limitation

We compared coaching and encouragement provided as IT or GT in women with POP over an 18-month period to evaluate whether IT could be a valid alternative to GT when the latter is not feasible. To our knowledge, no previous study has investigated this important issue in women with POP. The fact that the study was conducted during COVID-19 pandemic is also very relevant and adds strength to our conclusions since they are driven not just on artificially created experimental conditions but on real-life imposed external conditions.

We are aware that this study has a number of limitations. The primary outcome measure (ECOS 16) had a ceiling effect that limited its utility for the study. The study was conducted on women living in an urban area. Thus, generalization to populations of women living within different areas and male gender cannot be applied. We did not consider in the study modifications of nutrition[48] and sleep habits[49] (in particular during the pandemic) although they have been proven risk factors for severity of osteoporosis. Thus, further studies are needed to understand their influence on HRQoL of women with POP undergoing exercise programs. Since mineral bone densities of femur and lumbar spine were measured at baseline and used only as an inclusion criterion, we cannot demonstrate any effect of the exercise program on bone health. Finally, due to the COVID-19 restrictions, the drop-out rate from the study was high. This could have influenced the statistical significance of the results. However, the number of the women who concluded the study was 33, slightly under the sample indicated by the power analysis (36 women). A new post-hoc power analysis to confirm the sample power was performed. The new power analysis was conducted using ECOS-16 (primary outcome measure of the study) with the same specifics of the previous analysis (see Methods) but with an allocation ratio of 1.4 (to account for the difference between 14 subjects in one group and 19 in another). The sample power of our comparison was 0.76 indicating that our study population was within a reasonable range to provide statistically meaningful results.

Conclusion

IT and GT supervised exercise programs provide similar effectiveness, participation and safety to women with POP. Both approaches can be considered for implementation as public health measures dictate or when gym participation is not feasible due to environmental conditions, work or family limitations. Trainers have a crucial role not only to instruct participants to exercise correctly but also encourage them to continue to be active over time. Exercise protocols, even if based on supervised gym practice, must consider the possibility that a disruptive event (or, more simply, a change in a person's daily routine) could cause a sudden interruption of attendance at the gym and therefore necessitate the inclusion of educational plans to instruct participants to exercise effectively and safely without the direct supervision of a trainer.

Data Sharing Statement

The datasets generated and/or analysed during the current study are available from the corresponding author upon request.

Ethical Approval

The study was approved from the Local Ethics Committee (Comitato Etico Indipendente di Area Vasta Emilia Centro, CE-AVEC) of the Emilia-Romagna Region, in accordance with the 1964 Helsinki declaration and its later amendments. The trial was registered in ClinicalTrial.Gov (NCT04179903). Amendments of the study protocol induced by the COVID-19 outbreak were also approved by these same Local Ethics Committee.

Informed Consent

All the study participants gave their written informed consent after detailed information.

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Disclosure

The authors declare that they have no conflicts of interest in this work.

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