RESEARCH ARTICLE

A randomized controlled trial of center-based and home-based exercise programs among patients with rheumatoid arthritis

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ABSTRACT

Background: Rheumatoid arthritis (RA) patients benefit from aerobic and strengthening exercises.

Objective: To compare the effectiveness of a home exercise program against center-based aerobic and strengthening exercises on the grip strength, endurance, function, and fatigue among patients with RA.

Methodology: In this assessor-blind, randomized trial, 50 RA patients were assigned to either center-based physical therapy (CPT) or home exercise program (HEP) that included aerobic and strengthening exercises performed for four weeks. The grip strength, 6-minute walk test (6MWT), health assessment questionnaire-disability index (HAQ-DI), and the multidimensional assessment of fatigue (MAF) index were determined at weeks 0 (baseline), 2 and 4 weeks.

Results: Thirty-seven patients completed the study. All patients were females with a mean (±SD) age of 53 ± 11 years. The baseline characteristics were similar except for a higher pain intensity score in the CPT group ($p=0.02$). The grip strength of patients in both groups was low and did not change after four weeks. The 6MWT mean difference ±standard error (SE) was 21.39 ± 4.13 meters in CPT ($p<0.01$) and 9.46 ± 5.87 meters in HEP ($p=0.33$). Functional disability was mild with a mean difference ± SE of 0.38 ± 0.1 for CPT ($p<0.01$) and 0.15 ± 0.08 for HEP ($p=0.16$). The level of fatigue was moderate with a significant mean difference ± SE of 7.98 ± 1.71 for CPT ($p<0.01$) and 4.46 ± 1.14 for HEP ($p<0.01$). There was no significant between-group difference in the change in grip strength, 6MWT, HAQ-DI, and MAF index after four weeks of intervention.

Conclusion: Home-based and center-based physical therapy programs are comparable in improving endurance, function, and fatigue in patients with RA.

Keywords: *therapy, rheumatoid arthritis, fatigue, endurance, function, grip strength*

Introduction

Rheumatoid arthritis (RA) is a systemic autoimmune inflammatory disease. The prevalence varies between 0.3% and 1% and is more common in women and those living in developed countries. In the Philippines, the National Nutrition and Health Survey of 2003 puts the prevalence rate of RA at 0.6% [1]. These patients experience severe joint pain, decreased muscle strength, impaired physical function, and increased risk for cardiovascular disease [2,3]. Fatigue is another highly prevalent symptom (40-90%), considered second in importance to pain by RA patients, but most often overlooked by clinicians [4,5]. While the level of inflammation does not correlate with the level of fatigue, it magnifies the disability in patients with RA [6]. As a consequence of long-term joint damage and functional disability, at least 50% of those who suffer from developed countries cannot maintain a full-time employment [7].

The role of rehabilitation therapy in RA cannot be overemphasized. Both aerobic and resistance exercises are known to be effective non-pharmacological interventions to decrease fatigue in RA [8]. In one study, strengthening exercises

for two years resulted in improved Health Assessment Questionnaire (HAQ) scores [9]. The American College of Rheumatology recommends regular participation in dynamic exercises [10]. The American College of Sports Medicine (ACSM) advocates that aerobic exercises should be done three to five days per week and strengthening exercises 2-3 days per week, and continued long-term [11]. Despite the potential benefits of an exercise program for patients with RA, a very low number of doctors involved in the management of RA (17%) have the confidence to prescribe physical activity for their patients [12]. Participation in center-based physical therapy programs is costly, especially when the costs of transportation, time, and lost opportunity to earn are considered. An alternative to center-based physical therapy is a home exercise program where physiatrists instruct the patients on the proper techniques and monitor compliance to ensure effectiveness. Economic evaluations of tailored home-based programs among RA patients show that these are more cost-effective than the usual care leading to improved quality-adjusted life-year [13].

In the Philippines, the effectiveness of home exercise programs compared to center-based physical therapy programs has not yet been studied. The purpose of the study was to determine the effect of exercises performed as a center-based physical therapy program (CPT) compared to exercises performed as a home exercise program (HEP) on the grip strength, endurance, level of function, and level of fatigue among RA patients.

Methodology

Study Design and Ethics

This was an assessor-blind randomized controlled trial done from April 2014 to May 2015. Randomization and concealment allocation was prepared by an independent person by means of sealed, opaque envelopes. The study was approved by the UP Manila Research Ethics Board (RHB 2013-335-01) and was conducted according to the Good Clinical Practice Guidelines outlined in the Declaration of Helsinki.

Sample Size

Sample size was determined by power calculations for the four outcomes. The calculations were based on the following assumptions: anticipated mean grip strength of 15 and 10 kilograms (kg), anticipated mean endurance of 250 and 200 meters (m), anticipated effect of exercise on the mean level of function of 1 and 0.5, and anticipated mean level of fatigue of 20.7 and 19.2, for the two independent CPT and HEP groups, respectively [14-16]. With the alpha of 0.05 and, enrollment ratio of 1:1, the sample sizes ranged from 26 to 44. To account for potential drop-outs and withdrawals, the sample size was increased to 50, with 25 participants per treatment group.

Study Participants

Adult patients diagnosed with RA based on the 1987 American College of Rheumatology criteria were invited to participate in this four-week study. The patients had been referred to the rheumatology and rehabilitation medicine out-patient clinics of the Philippine General Hospital for diagnosis and therapy. They were ambulatory without an assistive device or lower extremity orthoses. Those with arthroplasty on weight-bearing joints, had none, minimal, or moderate severity of pain for the past seven days using the pain intensity numerical rating scale (NRS). The scale is a patient-reported pain rating with 0 (no pain at all) to 10 (worst imaginable pain) scores [17]. RA disease activity was assessed by the Disease Activity Score in 28 joints (DAS28) [18]. A score of less than 2.6 indicates remission, between 2.6 and 3.2 implies low disease activity, and a score of greater than 5.1 implies active disease. Patients were excluded if they had DAS28 >5.1; unable to tolerate exercise training due to cardiac or pulmonary disease; had NRS >6 on weight-bearing joints; had associated psychiatric illnesses such as but not limited to, schizophrenia, mood, and affective disorders and depression; and were engaged in regular exercise regimen 30 minutes a day, three times a week.

Outcome Measures

Assessments were done for all participants at weeks 0 (baseline), 2, and 4 of the exercise program by a blind assessor. The measurements were done prior to the initiation of the scheduled exercises for the day.

Grip Strength

Grip strength was measured using the Jamar® hand dynamometer, whose validity and reliability were proven in several studies [19]. With the patient on standard positioning, the dominant hand was used to squeeze the handle for three trials and the mean score taken. For Filipino males and females, the normative values standard deviation (SD) are 39.76 ± 7.567 kg and 26.68 ± 5.243 kg, respectively [20].

Endurance

Physical endurance was measured using the 6-minute walk test (6MWT). It is a reliable and valid test that reflects

the overall physical functional performance of an individual [21]. The participants were asked to walk over a hard, flat surface for a total of six minutes and the distance covered was measured. The walking distance of healthy subjects ranges from 400 to 700 meters (m) depending on gender, age, and height [22].

Level of Function

The function or disability was measured using the Health Assessment Questionnaire-Disability Index (HAQ-DI). This comprehensive measure of health outcome was considered the gold standard for the assessment of function in patients with RA [23]. The total HAQ score is the mean of the scores for the performance of 20 activities of daily living which ranges from 0 (minimum disability) to 3 (maximum disability).

Level of Fatigue

The symptom of fatigue was measured using the 16-item Multidimensional Assessment of Fatigue (MAF) questionnaire which covers the severity and timing of fatigue, amount of distress it causes, and its impact on the activities of daily living for the past seven days. The scores are expressed as global fatigue index which ranges from 1 (no fatigue) to 50 (severe fatigue) [24]. Normative data for healthy controls show a mean ±SD GFI of 17.0 ± 11.3 [25].

Training Programs

The participants randomized to the CPT group performed aerobic and strengthening exercises, supervised by a dedicated licensed physical therapist, as detailed in Table 1. Exercises were done two times per week for four weeks. Five to 10 minutes of warm-up and cool-down exercises were given. The physical therapist recorded the vital signs and any untoward events during the therapy on the Physical Therapy Notes.

The participants randomized to the HEP group performed aerobic and strengthening exercises at home after receiving written instructions that outlined exercises using improvised weights and materials, as detailed in Table 1. Any untoward event was recorded in a self-reporting home exercise diary. The duration of participation of both groups in the study was four weeks.

Table 1. *Comparison of intervention between the center-based physical therapy group and the home-based exercise program group*

	Center-based physical therapy group	Home-based exercise program group
Place of intervention	Out-patient Department	Participants' homes
Exercise program	Supervised by a physical therapist	Not supervised; Home exercises given as written instructions
Feedback	Physical therapist; Compliance monitored by physical therapist	Participants; Compliance monitored by self-reporting using a home exercise diary
Aerobic exercise	Mode: Stationary bicycle or lower extremity cycle ergometer, alternating with an upper extremity cycle ergometer Intensity: 40 – 60% of maximum heart rate Duration: 30 min/day Frequency: 2 days/week	Mode: Lower extremity cycle ergometer was replaced with walking, 30 minutes per day, 2 times a week or 15 minutes per day, 4 times a week Intensity: not controlled Duration: 30 mins/day or 15 mins/day Frequency: 2 times/week or 4 times/week
Strengthening exercise	Mode: Strengthening of major muscle groups of both upper extremity and lower extremities using dumbbells and ankle weights respectively, and grip strengthening exercises. Grip strengthening exercise was also given. Intensity: 30 – 60% of 1 repetition maximum, 1 set of 8 – 12 repetitions per exercise Duration: 30 min/day Frequency: 2 days/week	Mode: Strengthening of major muscle groups of both upper extremity and lower extremities using improvised weights such as a sand-filled mineral water bottle and homemade ankle weights. Grip strengthening exercises were given using a stress ball. Intensity: 1 set of 8 – 12 repetitions per exercise Duration: 30 mins/day or 15 mins/day Frequency: 2 times/week or 4 times/week
Baseline assessment	Week 0	
Follow-up	Reassessment after 2 and 4 weeks	
Duration of exercises	4 weeks	
Outcome measures	Grip strength, endurance, level of function, level of fatigue	

Data Analysis

Data were encoded and analyzed using Microsoft Excel and IBM SPSS Statistics 24. Descriptive statistics were used to describe the demographic characteristics of the study population and the outcome measures. Chi-square test or independent samples t-test was used to determine significant differences in the baseline characteristics between the two groups. Inferential statistics were done to determine if there were significant differences in the unit change from Week 0 to Week 4 within groups, using a t-test for two independent samples. Repeated measures analysis of variance were used to determine if there were significant differences in the outcome measures within and between each group. Sidak correction was used to adjust for multiple testing. The level of significance was set at 0.05. This study followed the per-protocol analysis.

Results

Participants

Fifty eligible participants were randomly allocated to either the CPT or HEP group. Of the 25 participants in the CPT group, five were lost to follow-up due to the following reasons: lack of time to undergo a one-hour session of physical therapy twice a week, work, or child-rearing responsibilities. In the HEP group, six participants were lost to follow-up, stating reasons cited above, with two participants not contacted due to unavailability of contact details. One participant was later excluded due to a diagnosis of major depressive disorder, while another participant withdrew due to the burden of further work-ups. In these instances where baseline data for a certain variable was present but follow-up data (Week 2 and Week 4) were absent, the participant was dropped out. A total of 37 participants (CPT, n=20 and HEP, n=17) were included in the analysis. The attrition rates for the CPT and HEP groups were 20% and 32%, respectively. The progress of participants through the study was depicted in Figure 1.

All participants were females with a mean ± SD age of 53 ± 11 years. Forty-four percent were of normal body mass index, while 46% were over the recommended weight for height. Only 10% were underweight. With regards to disease activity, 46% were in moderate disease activity, 30% were in low disease activity, while 24% were in remission. The proportion of participants with fatigue measured using the MAF was 97%.

Table 2 presents the demographic and clinical characteristics of the participants. At baseline, there were no significant differences between the two groups in demographic and clinical characteristics, except for pain intensity. The participants in the CPT group reported more intense pain (p=0.02).

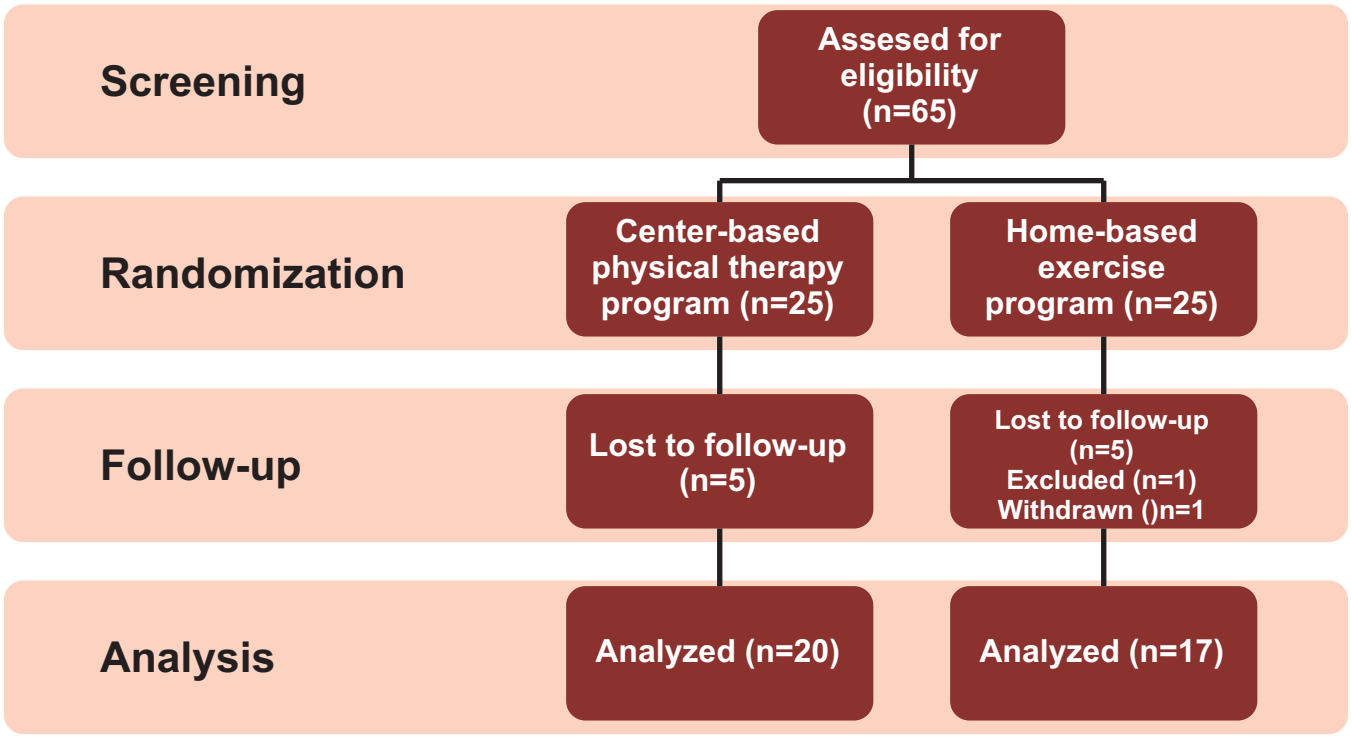

Figure 1. *Flow of participants*

Table 2. *Demographic and clinical data of 37 participants participating in the study*

Variable	Center-based physical therapy group (n=20)	Home-based exercise program group (n=17)	p-value*
Age, years	52 ±11	54 ± 12	0.52
Body mass index, kg/m2	23.1 ± 3.9	24.2 ± 4.6	0.33
DAS28 score	3.6 ± 0.9	3.2 ± 0.7	0.13
Disease duration, in years	8 ± 8	7 ± 5	0.53
Pain intensity, median (interquartile range)	4.5 (3-6)	3 (1.5-4)	0.02
Duration of fatigue, in years	2.5 ± 1.2	2.5 ± 1.1	0.87
Duration of sleep, in hours	5.4 ±1.5	6.1 ± 1.4	0.11
ESR, in mm/hr	37.4 ± 20.3	39.2 ± 22.7	0.76
Hemoglobin, in mg/dL	11.8 ±1.0	12.3 ± 1.2	0.14
Grip strength, in kg	11.6 ± 6.6	12.1 ± 5.8	0.79
Endurance, in meters	245.5 ± 37.8	252.2 ± 36.2	0.59
Function, HAQ-DI	0.9 ± 0.5	0.7 ± 0.4	0.08
MAF index	26.5 ± 9.8	23.4 ± 9.5	0.33

Values are means ± standard deviation unless otherwise stated.
DAS, disease activity score; ESR, erythrocyte sedimentation rate; HAQ-DI, health assessment questionnaire-disability index; MAF, multidimensional analysis of fatigue
*significant at <0.05.

Effect of Aerobic and Strengthening Exercises within and between Groups

Table 3 shows that the participants in both the CPT and HEP groups had improved fatigue scores after four weeks of therapy (p<0.01). While a trend towards improvement in the HEP group's endurance and function was observed, only those in the CPT group showed statistically significant improvement (p<0.01). Neither group had improvement in terms of grip strength.

Table 4 presents the between-group analysis for changes in grip strength, endurance, HAQ-DI, and MAF index showing no significant difference. There was no untoward event reported.

Discussion

This randomized controlled trial showed that a short-term program of aerobic and strengthening exercises significantly improved the level of fatigue among patients with RA. Furthermore, the participants in the supervised CPT group showed a statistically significant improvement in endurance and level of function. However, when compared to each other's performance, it was found that CPT and HEP had no statistically significant difference in their effects in improving grip strength, endurance, level of function, and level of fatigue.

The findings of this study further confirmed the established overall beneficial effects of exercise at all stages of RA, done

Table 3. *Outcome measures within groups before and after intervention*

Group	Parameter	Week 0	Week 2	Week 4	Mean difference weeks 2 and 0	p-value*	Mean difference weeks 4 and 0	p-value*
CPT n=20	Grip strength, kg	11.55	13.50	12.68	1.95±0.82	0.08	1.13±0.91	0.54
	Endurance, m	245.50	262.93	266.89	17.43±4.16	<0.01	21.39±4.13	<0.01
	HAQ-DI	0.93	0.69	0.55	-0.24±0.08	0.02	-0.38±0.10	<0.01
	MAF index	26.54	21.36	18.56	-5.18±1.12	<0.01	-7.98±1.71	<0.01
HEP n=17	Grip strength, kg	12.11	13.35	11.90	1.24±0.93	0.49	-0.21±0.83	0.54
	Endurance, m	252.20	266.44	261.66	14.24±4.33	0.01	9.46±5.87	<0.01
	HAQ-DI	0.65	0.53	0.50	-0.12±0.07	0.21	-0.15±0.08	<0.01
	MAF index	23.38	20.66	18.92	-2.72±0.87	0.02	-4.46±1.14	<0.01

CPT, center-based physical therapy; HEP, home-based exercise program; kg, kilograms; m, meters; HAQ-DI, Health Assessment Questionnaire-Disability index; MAF, Multidimensional Analysis of Fatigue.
* significant at <0.05

Table 4. *Outcome measures between the two groups before and after intervention*

Parameter	Center-based physical therapy (n=20)			Home-based exercise program (n=17)			Mean difference of change	p-value*
	Week 0	Week 4	Mean difference	Week 0	Week 4	Mean difference		
Grip strength, kg	11.55	12.68	1.13±4.05	12.11	11.90	-0.21±3.42	1.34±1.25	0.29
Endurance, m	245.50	266.89	21.39±18.49	252.22	261.66	9.46±24.22	11.95±7.03	0.10
HAQ-DI	0.92	0.55	-0.38±0.42	0.65	0.50	-0.15±0.31	-0.22±0.12	0.08
MAF index	26.54	18.56	-7.98±7.63	23.38	18.92	-4.46±4.17	-2.53±2.13	0.11

kg, kilograms; m, meters; HAQ-DI, Health Assessment Questionnaire-Disability index; MAF, Multidimensional Analysis of Fatigue.
* significant at <0.05

regularly and sustained for a long period of time [11,26,27]. Any significant improvements in strength, aerobic capacity, mobility, and disease activity, however, may be lost after discontinuation of exercise training as Hakkinen *et al.* have shown [28].

Our study population of Filipino patients with RA had a mean duration of illness of eight years which put them at high risk for the development of disability [29]. At baseline, our participants had grip strengths that were profoundly decreased compared to healthy subjects (11.6 ± 6.6 kg and 12.1 ± 5.8kg for the CPT and HEP groups, respectively, versus 26.7 ± 5.2 kg for healthy females) [20]. Hand grip strength is said to be a useful measurement for patients with RA, since the disease often results in functional deformities of the hands with consequent decrease in muscular strength [30]. It is considered an estimate of the body's overall muscle strength, a "robust predictor of functional decline, frailty, and mortality" [31]. After intervention, no improvement in grip strengths in both groups was found. This lack of response may be due to the relatively short treatment period as it takes at least four weeks of moderate to high-intensity resistance training for the body to undergo physiologic adaptations to exercise such as muscle hypertrophy [32]. Other studies demonstrated significant results in muscle strength only after at least 12 weeks of strengthening exercises [33].

In terms of endurance, the participants in both exercise programs covered distances that were way shorter than the 400 to 700 m that can be covered by healthy adults during the 6-minute walk test [22]. After intervention, only the supervised CPT group showed significant improvement in the distance covered. The performance of those in the HEP group significantly improved after two weeks but was not sustained after four weeks (Table 3). The performance of the task in this group may be affected by the following factors: variability of the walking surface used, frequency and type of encouragement they may have received during the act, number of turns in the course, and lack of direct supervision from medical personnel [34].

The recommended ACSM guidelines of 30-min walking sessions 3-5 times a week must be adhered to for longer-term benefits in aerobic capacity [11]. Other modes of aerobic exercises which may be done outside the clinic had been studied which included cycling, swimming, and dancing [8]. These exercises not only improved aerobic capacity and reduced cardiovascular risk in healthy adults but also improved muscle strength and joint mobility without aggravating disease activity. Joint tenderness and limitation of motion also decreased. Aside from improved physical function, these exercises also promoted better psychological and emotional well-being with decreased levels of depression, anxiety, and fatigue [8].

Patients who participated in this study reported mild disability at baseline. After intervention, only the CPT group showed significant improvement in their level of function with mean differences of -0.24 ± 0.08 after 2 weeks, and -0.38 ± 0.1 after 4 weeks (Table 3). These values were more than the minimum clinically important difference of 0.22 as determined by Wells *et al.* [35].The HEP group, on the other hand, showed no significant decrease in disability index. The findings in this group were supported by other studies which reported that in patients with a low disability index or low level of function at baseline, the HAQ-DI may not be as sensitive to change [15,27,36].

Fatigue is a central symptom in RA. It is both cause and effect of complications such as a decrease in the level of

function, productivity, cognitive and behavioral issues [37]. It has far-reaching consequences in the patients' lives, affecting personal, social, and emotional aspects. Many studies have demonstrated the different causalities and effects of fatigue, and its recognition by the patient and clinician is crucial if we are to address the secondary complication such as decrease in functional level [4-6,37]. The decrease in the level of fatigue in both CPT and HEP groups was statistically significant attesting to the beneficial and comprehensive effects of aerobic and strengthening exercises. This study reiterates the importance of assessing the level of fatigue of patients with RA and possibly other chronic illnesses, in every physician visit, with the use of the MAF scale or other valid fatigue measurement tools.

Despite the proven benefits of physical activity and the convenience of home-based exercise programs, 20% of the CPT group and 32% of the HEP group did not complete the program. This is comparable to the non-adherence rates of other studies which ranged from 20-40% [38-41]. Among the main barriers identified that lead to poor participation in physical activity among RA patients were the absence of proper advice and support from their managing rheumatology healthcare practitioners [38,42]. On the other hand, identified strategies that can improve adherence to HEP included clear instructions about the exercises, regular reminders and feedback sessions with a health care provider, and self-monitoring of progress through a patient diary [13].

Telerehabilitation can possibly be another venue for RA patients through which adherence to an exercise program can be improved. This strategy was seen to be effective and comparable to standard practice in the treatment of musculoskeletal conditions with reports of high to very high patient satisfaction [43,44]. Instructions on the proper execution of home-based exercises can be delivered through videoconferencing with return demonstration of patients. It allows exchange of feedback between care-givers and patients and timely monitoring of treatment outcomes. This shift is an important behavioral change that healthcare institutions should anticipate. A change in healthcare access preference may also be expected as the demography of both healthcare providers and receivers shift towards the digital-native younger generation.

Conflicts of Interest

The authors disclose that they do not have any conflicts of interest.

Funding Statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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