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Comparison of Pilates and Hydraulic Circuit Training in Women

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This Scholarly Project, submitted by Shauna Differding, Sandra Hoff, and Sara Murray in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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PERMISSION

Title Comparison of Pilates and Hydraulic Circuit Training in Women

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Degree Doctor of Physical Therapy

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Signature(s) Shauna Dufford
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Date 12.14.06

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ABSTRACT

Introduction: Obesity continues to be a rising problem in the United States. Women typically are the majority of consumers in weight treatment programs. Due to conflicts with time and social roles, they struggle to remain committed to an exercise program. Most women enter into weight treatment programs not for health, but rather for appearance.

Purpose: The purpose of this study is to evaluate the effects of cardiovascular function, flexibility, strength and circumferential measurements between mat Pilates and hydraulic circuit training over a six-week period. The benefits of these comparisons will help women find an effective and efficient fitness program. As the physical therapy field continues to advance into preventative healthcare, this study will provide information to physical therapists and consumers regarding wellness in women. This is important to aid in the prevention of possible injuries, co-morbidities and regain overall quality of life. These two programs were chosen for this study as they have increased in popularity in recent years.

Methods: Nine healthy female subjects over the age of 18 who were beginners in their respective exercise program were included in this study. Six subjects were in the hydraulic circuit training group and three were in the mat Pilates group. Areas being assessed include vital signs, strength, flexibility and circumferential measurements. These assessments were completed within one week of initiation of chosen program (initial) and six weeks later (final).

Results: The results of this study were based on only seven of the subjects. This study found that there were no significant differences between groups from initial and final measurements. There was a significant difference in strength of left elbow flexion, flexibility and bust circumference in the hydraulic circuit training group from initial to final measurements. No statistical analysis was completed for the mat Pilates group as the sample size was too small. However, certain trends were noted.

Conclusion: The results from this study show there are no significant differences between the hydraulic circuit training and Pilates groups. However, trends were seen in each group that shows the benefits of physical activity. Future studies in this area would be beneficial especially with longer follow-up periods to see the effects of these two exercise programs.

CHAPTER I

INTRODUCTION

Due to physical appearance concerns, the majority of consumers for weight treatment programs are women. Most health care providers often assume the desire for weight reduction is for health benefits and the most common way to judge the effectiveness of a program is to look at the number of pounds lost.[1] However, most women enter into weight treatment programs not for health, but rather for appearance.[1] Pilates and hydraulic circuit training appear to be growing in popularity, especially in the special population of women. The benefits of a successful fitness program should not only focus on weight reduction and appearance, but also include cardiovascular function, flexibility and strength, among other things.

Problem Statement

Although there are numerous studies regarding weight loss and benefits of exercise, there is limited research addressing the fitness programs of Pilates and hydraulic circuit training in women. No studies have been found comparing these two fitness programs in the areas of cardiovascular function, flexibility, strength and circumferential measurements. Without this knowledge, it is difficult to determine an effective and efficient exercise regimen for women.

Purpose of Study

The purpose of this study is to evaluate the effects of cardiovascular function, flexibility, strength and circumferential measurements between mat Pilates and hydraulic circuit training over a six-week period. The benefits of these comparisons will help women find an effective and efficient fitness program.

Significance of Study

As the physical therapy field continues to advance into preventative healthcare, this study will provide information to physical therapists and consumers regarding wellness in women. This is important to aid in the prevention of possible injuries, co-morbidities and regain overall quality of life. Pilates has been recently utilized more often in physical therapy than in the past.[2] Hydraulic circuit training is the form of exercise utilized at Curves fitness centers. Curves is increasing in popularity because everything from the environment to the equipment has been designed specifically for women.[3] Due to the lack of research in these areas, this study will attempt to provide evidence of Pilates and Curves being effective rehabilitative and preventative tools.

Research Questions

1. Is there a significant difference in hydraulic circuit training and mat Pilates comparing strength, flexibility, circumferential measurements and cardiovascular function?
2. Do strength, flexibility, circumferential measurements and cardiovascular function improve with either program?

Hypothesis

Null Hypothesis: There is no significant difference in strength, flexibility, circumferential measurements, and cardiovascular function between hydraulic circuit training and mat Pilates after a six week program.

Alternative Hypothesis: There is a significant difference in strength, flexibility, circumferential measurements, and cardiovascular function between hydraulic circuit training and mat Pilates after a six week program.

CHAPTER II

LITERATURE REVIEW

Fitness

Obesity continues to grow in the United States and does not appear to be slowing down in the future. This epidemic of obesity is associated with decreased quality of life (QOL) and disability in basic activities of daily living (ADLs).[4] Physical fitness is an important part of remaining healthy throughout the years. Weight fluctuations, defined as continued weight loss and gain over periods of time, can occur due to many different factors such as certain underlying medical conditions or unsuccessful dieting. Roughly one-third of men and one-half of women are currently trying to lose weight, with only 5%-20% of those being able to keep the weight off permanently.[5] Weight fluctuations are associated with a significantly increased risk of cardiovascular disease mortality in the adult US population.[5] Health care providers should be more aggressive to promote maintenance of weight loss and avoid weight fluctuations.[5]

Regaining a healthy life needs to be a part of a new lifestyle, not a short-term commitment. This new lifestyle should consist of a healthy diet combined with regular physical activity. Diet combined with exercise has been shown to provide a greater weight loss, especially initially, when compared to diet or exercise alone.[6,7] Some of the other health benefits of exercise include reduction in cardiovascular risk factors, increased glycemic control in diabetics, decreased blood pressure, decreased LDL cholesterol and increased HDL cholesterol.[6]

Exercise can have an overall effect on the entire body. It not only improves physical health but can impact mental health for many individuals. The frequency of

mental disorders, most of which are anxiety and depression, in one month's time was measured to be approximately 15.4% in the United States.[8] Physical activity has been shown to enhance mood and self-esteem with aerobic exercise having the greatest effect, followed closely by resistive exercise.[8,9] Single episodes of vigorous exercise have been found to reduce anxiety for up to 2-4 hours after exercise, which is longer than quiet rest.[8,9] Similar results were found with a long-term exercise program.[8,9] Changes in mental health disorders following an exercise program are more easily seen in people who have already been diagnosed. Exercise has also been used as an effective preventative measure for those who currently don't have a diagnosis of a mental health disorder.[8] The effect of physical activity on depression is dependent on the severity, but clinically depressed participants showed larger decreases in depression as a result of physical activity.[9]

Women and Fitness

In society today, thinness is associated with beauty and health.[1] Western cultures focus most of this body image towards women, but women are most likely to criticize other women in this area.[10] Thus, this finding suggests weight is more of a central aspect in women's lives. Body dissatisfaction is statistically higher among women as women are more critical of their body weight than men.[10] Women often feel that they need to lose weight for appearance reasons instead of for health reasons.[1] This interpretation shows women place weight as a defining aspect of their personal value. Because of this aspect, overweight women have been found to have lower self-esteem levels when compared to women of normal weight.[10]

One study by Lopez[1] has shown that women reported there is a conflict of values with staying true to an exercise program and maintaining their normal everyday life. Women felt that staying with the exercise program decreased their overall quality of life because it affected their social roles as mother and wife. Current weight treatment programs often do not meet the expectations of women's values and needs.[1] Many women feel the time commitment, loss of spontaneity and loss of control of choices in food and type of exercise cause them to be unsuccessful with weight treatment programs.[1]

An increased abdominal circumference has been linked to an increased risk of cardiovascular mortality in both men and women.[7] By reducing the amount of visceral fat within the body, these cardiovascular risks can be decreased.[7] Men usually lose greater amounts of weight when doing life-style modifications than women.[7] This is typically due to similar caloric intake between men and women, when in reality men and women have different caloric requirements. In a study by Wirth and Steinmetz,[7] men were allotted 1500 kcal/day and women were allotted 1200 kcal/day on a low calorie diet. Even though men and women are capable of losing relatively the same amount of weight, it has been shown that men lose significantly larger amounts of weight than women. Specifically to this study, men lost an average of 7.3 kg whereas women lost on average 4.6 kg. Therefore, in losing more weight, men also decreased cardiovascular risk factors.[7]

Men have been shown to have significantly greater strength and power in both upper and lower extremities when compared to women, whether in normal weight or overweight groups.[4] Because of this factor, women were significantly more influenced

by the sex of the members when choosing an exercise facility.[11] Women-only fitness centers can provide a comforting environment for those women who are overweight, conscious about their body appearance and unhappy with their body images.[12]

As self-image is a major component of how women view themselves, improving this is an important goal for not only women but health care providers as well. It has been shown that strength training improves self-image and attitude towards oneself, even if there might be a gain in weight.[13]

Hydraulic Circuit Training

Hydraulic circuit training consists of eight to twelve exercises performed in a specific sequence. Exercises are performed on machines in which the velocity of work determines the resistance.[14] Hydraulic circuit training is based on fluid-filled cylinders which do not have a preset speed, but instead rely on the speed at which the individual is able/wants to contract their muscles. The harder and faster the muscles are contracted, the more difficult the resistance will be.[15] Each exercise is performed for a given amount of time (usually short bouts of 30-60 seconds). The exercises usually involved in many hydraulic circuit training programs include elbow flexion and extension, knee flexion and extension, hip abduction and adduction, trunk rotation, trunk flexion and extension and shoulder press.[14] The circuit consists of alternating rest stations and resistance stations.[14] The rest station can either be aerobic activities to maintain elevated heart rate or can be a recovery station as determined by the participant. One study by Takeshima et al[16] has shown a significant increase in cardiovascular fitness as well as increased strength and decreased body fat with hydraulic circuit training combined with aerobic stations.[16]

Hydraulic circuit training is usually done with a submaximal force which ranges from 40-60% of maximal force. The overall effect of hydraulic circuit training on cardiovascular fitness is still being debated, however one study found a decrease in resting heart rate.[14] According to Haennel et al,[14] this decrease in heart rate could be attributed to a combination of increased parasympathetic tone and decreased sympathetic activity. In order to achieve this result, an intensity of at least 60% of the heart rate reserve must be achieved throughout the entire workout. A submaximal force during hydraulic circuit training combined with the 60% heart rate reserve was shown to increase cardiovascular function.[14]

Pilates

Pilates was founded by Joseph H. Pilates and brought to the US in 1923.[2] Pilates is a workout that aids in flexibility, strength, endurance and coordination without causing muscle bulk. The primary emphasis of Pilates is incorporating controlled movements which engage the body and mind. These exercises focus on the core muscles, also referred to as the "powerhouse." The core muscles include rectus abdominus, internal and external obliques, transverse abdominus, quadratus lumborum, erector spinae group (back extensors), iliopsoas (hip flexor) and other hip musculature.[17]

There are two forms of Pilates currently used today which include floor exercises and spring driven apparatuses. There are eight basic principles incorporated into Pilates which include concentration, control, precision and coordination, isolation and integration, centering, flowing movement, breathing and routine. Through the work of a Pilates education company, they have combined the above eight principles into six.

Principle one is breathing and helps stabilize the spine and extremities throughout the exercise movements. Principle two is axial elongation/core control which incorporated Pilates concept of centering. This principle obtains optimal orientation of the spine in order to provide movement which avoids undue stresses on the body and allows for more efficient movement of the body. Principle three is efficient organization of head, neck and shoulder girdle which integrate the flowing movement from the early Pilates principles. The benefits of this principle include increased range of motion (ROM), energy conservation and decreased risk of injury. Principle four is spine articulation which was formally isolation and integration. Although controversial, research has shown that this principle can increase movement of hypomobile segments, while at the same time decrease movement at the hypermobile segments.[2] In doing this, it provides equivalent distribution of movement and shear forces to the spine. Principle five is alignment and posture incorporating centering, precision and coordination. With correct alignment and posture, the body expends less energy doing everyday tasks and decreases risk of early fatigue, abnormal stresses and faulty movements of the body. Although static posture is always a concern, Pilates focuses more on the dynamic posture as most of the day is spent moving rather than standing still. Principle six is movement integration combining concentration, integration, flowing and routine. Many Pilates rehab specialists believe this is the most important principle and creates a relationship between the mind and body. This phenomenon could possibly explain the primary reason for Pilates success.[2]

Due to these principles, it has become popular in the rehab setting because it allows early movement without destructive forces which can quicken recovery. By

offering a flexible environment, the client is able to achieve successful movements with less fatigue, less effort and greater movement awareness retention.[2]

All populations including athletes, people with medical conditions such as rheumatoid arthritis and chronic pain, as well as with healthy individuals, can use Pilates.[18]

CHAPTER III

METHODS

Subjects

Nine healthy female subjects agreed to participate in this study. All participants were over the age of 18 and enrolled in either a Curves or mat Pilates fitness program. Subjects were informed of the testing procedure and their rights in accordance with the Institutional Review Board Procedures at the University of North Dakota (IRB-200608-037, see Appendix A) and Altru Health Systems (ST-24, see Appendix B). A signed consent form was received from each participant (see Appendix C) and the participant was given a copy. Subjects were screened by a verbal intake form (see Appendix D) and were excluded if they had a personal history of cardiac disease, were currently pregnant, were currently training for any collegiate athletics, participated in this type of program within the last year and participated in moderate (30-45 minutes) physical activity more than 3 times per week. These exclusions were made for the safety and homogeneity of all participants.

All participants were participating at either Curves, which specializes in hydraulic circuit training for women, or a mat Pilates class at Altru Fitness. They were assessed at their respective facilities within one week of starting the program and six weeks later.

Instrumentation

Instrumentation for this scholarly project included the following: sphygmomanometer (blood pressure cuff), stethoscope, stopwatch, Microfet, goniometer, sit-and-reach box and standard tape measure (see Figures 1, 2 and 3).

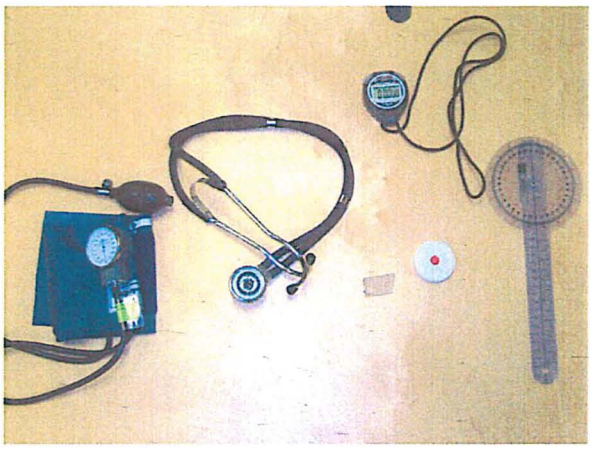

Fig. 1. Blood pressure cuff, stethoscope, stopwatch, tape measure, goniometer

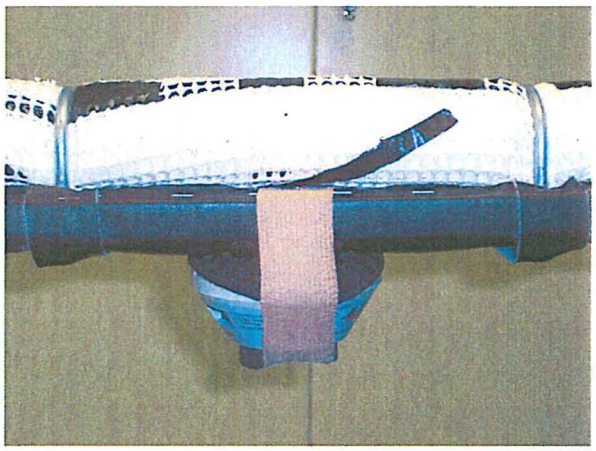

Fig. 2. Microfet

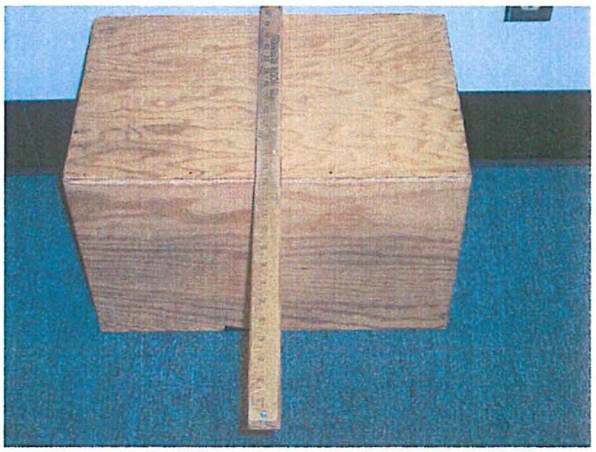

Fig. 3. Sit-and-reach box

Blood pressure was assessed using a sphygmomanometer and a stethoscope. Heart rate was assessed manually for 60 seconds as timed by a stopwatch. Strength testing was measured using a Microfet hand-held dynamometer (Hoggan Health Industries, Draper, UT) for elbow flexion and knee extension. Elbow flexion and knee extension angles were measured using the universal goniometer prior to strength testing. Sit-ups were performed to assess abdominal strength. Hamstring flexibility was measured using the sit and reach box. The sit and reach is measured with a yardstick attached to the top of a box which is placed against a wall on the floor. Circumferential measurements were taken using a standard tape measure.

Blood pressure was assessed using the sphygmomanometer and stethoscope and heart rate was assessed using the radial pulse, as these are universally accepted methods used in most medical practices. The Microfet was used to assess strength, as this was the most portable device and only instrument for objectively testing strength that was accessible. Placement of the Microfet was at the distal wrist crease and was done in accordance similar to the study of Allred, et al.[19] This study found that measuring strength at either the distal wrist crease or midpoint of the forearm is reliable as long as placement remains consistent. Knee extension strength was measured at a 45° angle as this was the halfway point in the peak torque range of 30-60°, on a scale of 0-90° of knee flexion. This measurement was assessed with EMG and isokinetic testing and was cited by Reichard, et al.[20] The sit and reach technique was used because it has been shown to have criterion-related validity as a test of hamstring flexibility.[21] This method offers more reproducible data when compared to the universal goniometric measurement.[22] For

girth measurements, the standard tape measure was used due to accessibility of the areas being assessed.

Procedure

After the initial intake form was completed to determine eligibility requirements, all participants then signed an informed consent prior to the start of any testing. All measurements were taken within the first week of starting the chosen fitness program and after six weeks of participation for comparison of results. At the initial and final evaluations, the strength of elbow flexion and knee extension using the Microfet and flexibility of hamstrings using the sit-and-reach box were performed three times with an average being recorded. Vital signs, sit-ups and circumferential measurements were completed only one time at initial and final evaluations and recorded. Prior to any measurements being recorded, specific verbal instructions were given to each participant and were station dependent. The same examiner did each test with all subjects at both the initial and final evaluations.

Vital signs, including heart rate and blood pressure, were assessed manually in sitting and before any other measurements were taken. Heart rate was evaluated using the radial pulse and was assessed with the second and third digits of the researcher's hand for a 60 second count, timed with a stopwatch. Blood pressure was taken on the right arm using a stethoscope and sphygmomanometer while the subject was seated in a chair. The arm of the participant was slightly bent and sphygmomanometer was place snuggly around the upper arm with the stethoscope placed over the brachial artery. Subjects' legs were uncrossed with feet placed flat on the ground. After vital signs were taken, the

participant rotated through three stations; strength, flexibility, and circumferential measurements.

The Microfet was fixated onto a hand-made steel platform with an adjustable bar (see Figure 4 and 5). Subjects were then asked to sit in a rigid chair with their shoulders in a relaxed neutral position, the upper arm adducted to their side, forearm supinated, and elbow flexed to 90° (see Figure 6). Placement of the Microfet was placed at the distal wrist crease. The subject was instructed to push with maximal isometric force against the stabilized Microfet for three seconds. All subjects were given the same directions of "one, two, three, push. one, two, three, rest." Each trial was repeated three times bilaterally and a rest period of 30 seconds, as timed by a stopwatch, was given between trials. An average was taken from the three trials and recorded.

While the participant was still seated in a rigid chair, they were placed in a 45° angle of knee flexion and the adjustable bar was lowered for proper placement (see Figure 7). For placement of the Microfet, a standard tape measure was used to measure three centimeters proximal to the medial malleolus (see Figure 8). A reference mark was placed on the subject's skin to ensure accurate placement of the Microfet for repeated trials. Instructions were given to the participant to sit back in the chair and hold onto the bottom of the chair. After alignment of Microfet at the reference point, participants were instructed to kick with maximal isometric force against the stabilized Microfet. All subjects were given the same instructions of "one, two, three, kick. one, two, three, rest." Each trial was repeated three times bilaterally and a rest period of 30 seconds, as timed by a stopwatch, was given between trials. An average score was recorded based on the results from the three trials.

Fig. 4. Hand-made steel platform at top level

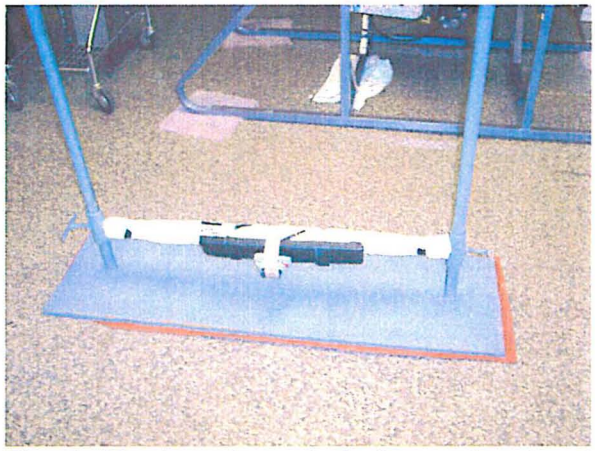

Fig. 5. Hand-made steel platform at low level

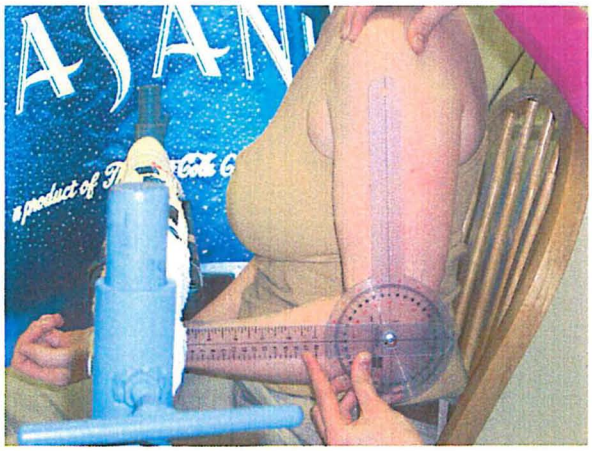

Fig. 6. Elbow flexion set-up

Abdominal strength was measured using sit-ups done in a supine position on the floor. The participant was instructed to cross both arms over her chest and bend her knees to bring the feet flat on the floor. Pressure was given at the feet by the researcher to stabilize the lower body. Sit-ups were performed for a 30 second period, timed by stopwatch, with the subject trying to achieve a maximal amount of sit-ups during this time. The sit-up was counted if the elbows touched the thighs and returned to the starting position of the scapula on floor. All participants were instructed of this technique (see Figures 9 and 10).

The sit-and-reach technique consisted of the participant sitting on the floor with knees straight and feet up against the box. The participant placed one hand on top of the other (see Figures 11 and 12). Specific instructions stated "on the count of three, reach forward as far as possible while keeping your knees straight and hold for 3 seconds without bouncing." Once the participant had reached as far forward as possible and held for three seconds, the measurement was recorded in centimeters where the tip of the third digit reached. Each trial was repeated three times and a rest period of 30 seconds, as timed by a stopwatch, was given between trials. The three trials were averaged and recorded as the final measurement.

Circumferential measurements assessed the fullest part of the bust, top of the iliac crest, around the greater trochanters, and around each thigh just below the gluteal fold (see Figures 13, 14, 15 and 16). Measurements were taken once at each landmark and measured in centimeters.

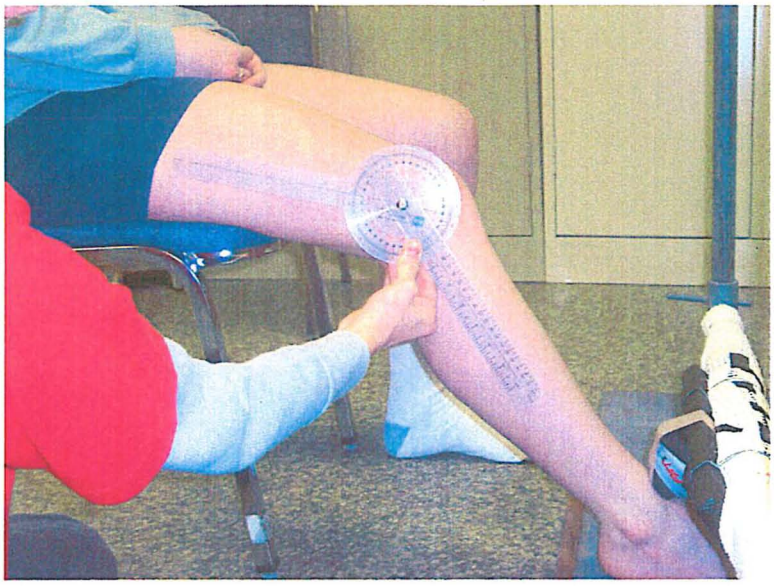

Fig. 7. Knee extension set-up

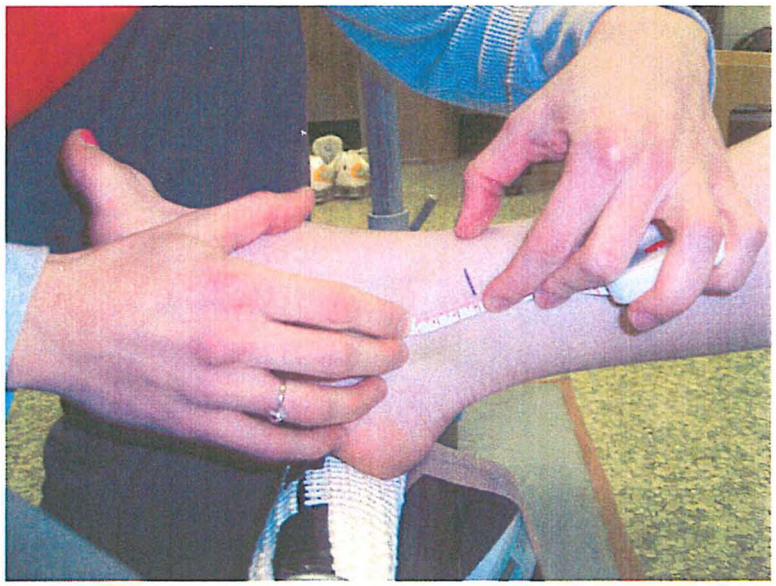

Fig. 8. Measurement with tape measure and reference mark for Microfet placement

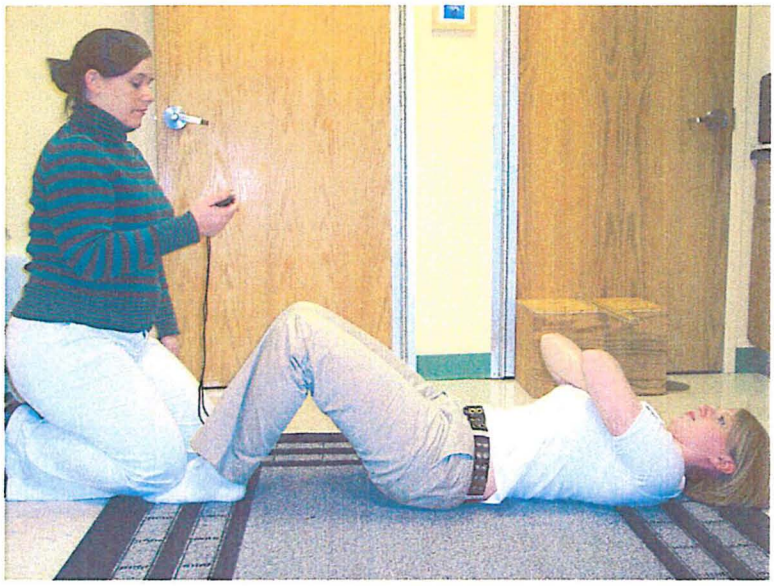

Fig. 9. Beginning position of sit-ups

Fig. 10. Ending position of sit-ups

Fig. 11. Beginning position of sit-and-reach

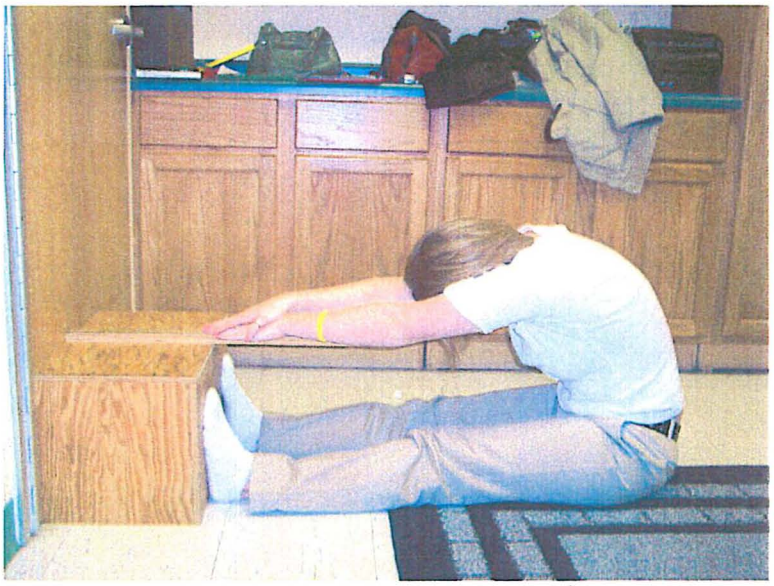

Fig. 12. Ending position of sit-and-reach

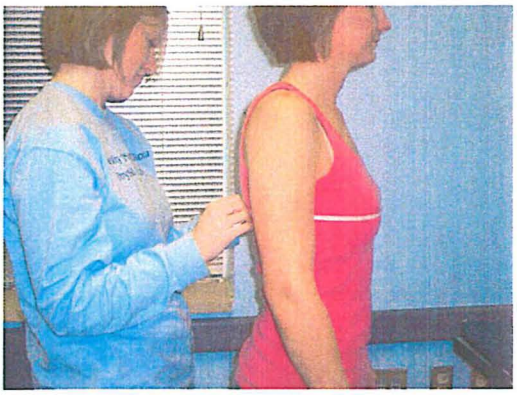

Fig. 13. Bust circumference

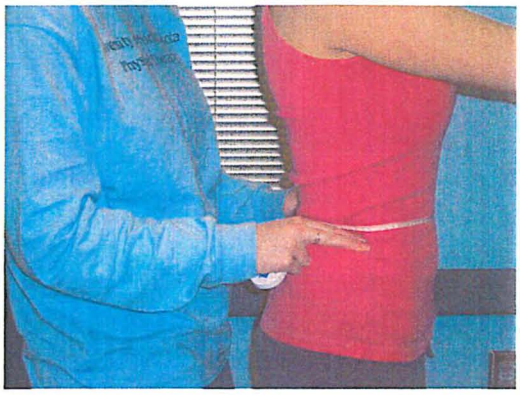

Fig. 14. Iliac crest circumference

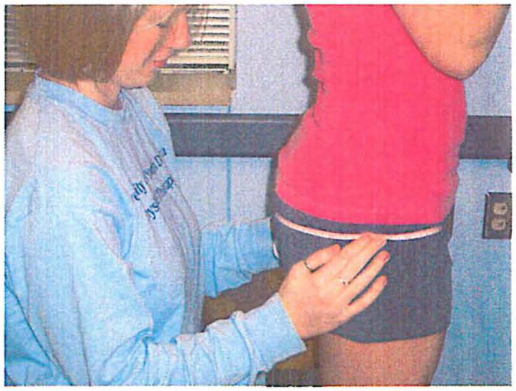

Fig. 15. Greater trochanter circumference

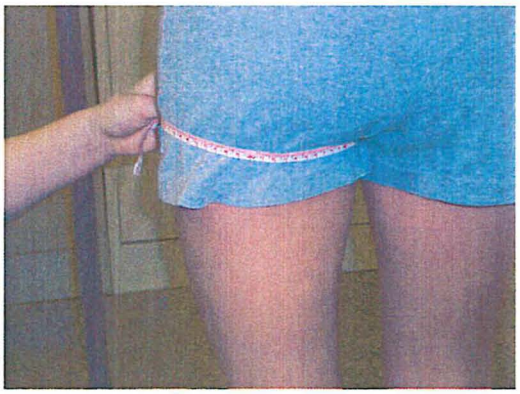

Fig. 16. Thigh circumference

CHAPTER IV

RESULTS

Statistical Analysis

There were nine healthy females who agreed to participate in this study. Out of the nine, only seven completed the respective six-week program. One participant of each program was not included in the final analysis due to completing less than 50% of the desired program. Attempts to contact these two participants for follow-up measurements were unsuccessful.

Initial measurements between the hydraulic circuit training group and the Pilates group showed no significant differences in any of the measurements. The mean, standard deviation (SD), t-statistic (t), degrees of freedom (df), and level of significance (p) are reported in Table 1.

Final measurements between the hydraulic circuit training group and the Pilates group showed no significant differences in any of the measurements. The mean, standard deviation (SD), t-statistic (t), degrees of freedom (df), and level of significance (p) are reported in Table 2.

The results were then compared from initial measurements to final measurements within the same fitness program. To find these results a repeated-measures (RM) ANOVA was performed. The results for the hydraulic circuit training group showed no significant difference between initial and final readings of resting heart rate, blood pressure, right elbow flexion, right and left knee extension, sit-ups, at the iliac crest, greater trochanter, or right and left thigh circumferential measurements. There was a significant difference found in the hydraulic circuit training group in left elbow flexion

strength, sit and reach measurement, and bust circumferential measurement as shown in Table 3. The repeated-measures ANOVA was not performed with the Pilates group due to the small sample size available.

Table 1. Mean, SD, IM t test for Comparisons between Groups at Initial.

Measurement	Program	n	Mean	SD	t	df	p
R elbow flexion(lbs)	Curves Pilates	5 2	23.20 24.50	6.42 2.12	-.267	5	.800
L elbow flexion(lbs)	Curves Pilates	5 2	22.73 24.34	6.83 2.35	-.309	5	.770
R knee extension (lbs)	Curves Pilates	5 2	28.73 37.16	8.47 5.89	-1.256	5	.265
L knee extension (lbs)	Curves Pilates	5 2	25.53 36.33	6.41 0.00	-2.250	5	.074
Sit and reach (cm)	Curves Pilates	5 2	38.4 47.25	10.12 15.20	-.934	5	.393
Bust circumference (cm)	Curves Pilates	5 2	103.16 93.00	11.44 4.24	1.713	4.904	.148
Iliac crest circumference (cm)	Curves Pilates	5 2	94.80 83.65	11.96 6.58	1.201	5	.283
Greater trochanter circumference (cm)	Curves Pilates	5 2	110.22 102.05	5.40 8.13	1.615	5	.167
R thigh circumference (cm)	Curves Pilates	5 2	62.88 59.80	3.10 4.81	1.048	5	.343
L thigh circumference (cm)	Curves Pilates	5 2	62.96 59.50	3.00 5.52	1.134	5	.308
SPB (mmHg)	Curves Pilates	5 2	122.80 119.00	6.87 4.24	.706	5	.512
DBP (mmHg)	Curves Pilates	5 2	79.20 77.00	7.56 7.07	.352	5	.739
RHR (bpm)	Curves Pilates	5 2	72.40 67.50	9.26 10.61	.613	5	.566
Sit-ups in 30 seconds	Curves Pilates	5 2	9.60 16.50	3.78 7.78	-1.170	5	.150

Table 2. Mean, SD, IM t test for Comparisons between Groups at Final.

Measurement	Program	n	Mean	SD	t	df	p
R elbow flexion(lbs)	Curves Pilates	5 2	26.86 27.50	3.60 1.17	-.233	5	.825
L elbow flexion(lbs)	Curves Pilates	5 2	26.60 27.67	4.97 2.83	-.277	5	.793
R knee extension (lbs)	Curves Pilates	5 2	32.27 37.16	10.97 9.67	-.546	5	.608
L knee extension (lbs)	Curves Pilates	5 2	34.80 41.66	9.04 6.60	-.953	5	.384
Sit and reach (cm)	Curves Pilates	5 2	41.70 47.75	9.93 16.62	-.624	5	.560
Bust circumference (cm)	Curves Pilates	5 2	102.22 91.60	11.75 4.24	1.755	4.935	.140
Iliac crest circumference (cm)	Curves Pilates	5 2	93.98 80.70	12.55 6.22	1.372	5	.228
Greater trochanter Circumference (cm)	Curves Pilates	5 2	109.16 100.75	4.45 5.73	2.125	5	.087
R thigh circumference (cm)	Curves Pilates	5 2	62.24 59.50	3.91 4.53	.811	5	.454
L thigh circumference (cm)	Curves Pilates	5 2	62.34 59.30	3.70 4.95	.912	5	.404
SBP (mmHg)	Curves Pilates	5 2	119.20 117.00	5.40 1.41	.539	5	.613
DBP (mmHg)	Curves Pilates	5 2	77.20 76.00	4.82 2.83	.319	5	.762
RHR (bpm)	Curves Pilates	5 2	70.00 65.50	5.52 10.61	.611	5	.568
Sit-ups in 30 seconds	Curves Pilates	5 2	12.00 19.00	3.00 7.07	-1.352	1.148	.383

Table 3. Means, SD, and RM ANOVA for Curves, Comparison of Initial and Final

Measurement	Time	n	Mean	SD	F	df	p	η^2	Power
R elbow flexion(lbs)	Initial Final	5 5	23.20 26.86	6.42 3.60	4.157	1,4	.111	.510	.346
L elbow flexion(lbs)	Initial Final	5 5	22.73 26.60	6.83 4.97	8.601	1,4	.043*	.683	.601
R knee extension (lbs)	Initial Final	5 5	28.73 32.27	8.47 10.97	.432	1,4	.547	.097	.081
L knee extension (lbs)	Initial Final	5 5	25.53 34.80	6.41 9.04	6.377	1,4	.065	.615	.485
Sit and reach (cm)	Initial Final	5 5	38.40 41.70	10.12 9.93	9.348	1,4	.038*	.700	.635
Bust circumference (cm)	Initial Final	5 5	103.16 102.22	11.44 11.75	11.242	1,4	.028*	.738	.710
Iliac crest circumference (cm)	Initial Final	5 5	94.80 93.98	11.96 12.55	3.306	1,4	.143	.452	.288
Greater trochanter circumference (cm)	Initial Final	5 5	110.22 109.96	5.40 4.45	1.221	1,4	.331	.234	.138
R thigh circumference (cm)	Initial Final	5 5	62.88 62.24	3.10 3.91	.663	1,4	.461	.142	.098
L thigh circumference (cm)	Initial Final	5 5	62.96 62.34	3.00 3.70	.710	1,4	.447	.151	.101
SBP (mmHg)	Initial Final	5 5	122.80 119.20	6.87 5.40	1.385	1,4	.305	.257	.150
DBP (mmHg)	Initial Final	5 5	79.20 77.20	7.56 4.82	.455	1,4	.537	.102	.083
RHR (bpm)	Initial Final	5 5	72.40 70.00	9.26 5.52	.380	1,4	.571	.087	.077
Sit-ups in 30 seconds	Initial Final	5 5	9.60 12.00	3.78 3.00	6.700	1,4	.061	.626	.503

*Significance (p) based upon $\alpha < 0.05$

CHAPTER V

DISCUSSION

Due to the small sample size, the results of this study are not being generalized to the population as a whole. The results that were reported are general trends that were seen with this sample. As described previously, there were no significant differences in all areas measured between the Curves hydraulic circuit training and Pilates group at both initial and final measurements.

The trends generally seen within the Pilates group are slight increases in right elbow flexion and left knee extension strength and number of sit-ups completed. There were slight decreases in bust circumference, iliac crest circumference and right thigh circumference as well as resting heart rate. No conclusions can be stated about left elbow flexion, right knee extension, flexibility, greater trochanter circumference, left thigh circumference and blood pressure as there were mixed results between the two participants.

The results in the Curves group between initial and final measurements showed significant differences in left elbow flexion strength, flexibility and bust circumference. The strength gain in the left elbow could possibly be due to the fact that the majority of people are right hand dominant and primarily use their dominant hand for most activities; therefore, a greater strength gain would be seen in the left when compared to the right. Curves emphasizes the importance of stretching before and after the workout routine, which could lead to the significance found in flexibility. There were no conclusions regarding significant differences in all other measurements through the repeated-measures ANOVA. This pilot study is the first of its kind and therefore the results are

unable to be compared to previous studies. Continuation of both programs, along with follow- up evaluations after the initial six-week trial, could yield more and even greater physical changes.

Limitations and Future Recommendations

There were several limitations to this study. First, there was a limited amount of participants who volunteered for this study. A larger number of participants (greater than 30 subjects) could have produced better statistical representation of the population as a whole. The number of participants in each group was not equal, as there were a total of five subjects in the hydraulic circuit training program and only two in the mat Pilates group. Secondly, the recruitment process had challenges due to the time of the study and miscommunications between the researchers and facilities. One facility stated a larger increase in new memberships during the months leading up to the summer season. Recruitment, however, was unable to start this early and took place in late summer/early fall. Miscommunications occurred because researchers communicated with only two people for all of the hydraulic circuit training facilities. There are many employees at these facilities that were unaware of this project and recruitment procedures.

Age was not taken into consideration for either group. This could greatly affect the results because there may be differences as related to age. The effects of aging that may be a factor in the results of this study include a slower metabolism, nutritional concerns regarding absorption and there could be less activity due to the likelihood of co-morbidities. Another limitation is the standardization of clothing for circumferential measurements. These measurements were taken over the workout clothes which could vary from initial measurement to final measurement. The compliance of the participants

was not formally assessed but rather based upon an honor system subjectively provided by subjects. Finally, due to the lack of research comparing these two forms of exercise, we were unable to compare results with prior studies and there were many hurdles to overcome with this study.

Future recommendations to improve this study would be to include a more efficient and effective recruitment process to increase the number of participants. To ensure all employees at the respective facilities are knowledgeable about the study, the possibility of attending a staff meeting to explain the study and recruitment procedures may eliminate some communication barriers. Standardization of clothing or use of a private room to allow for measurements to be taken on skin at initial and final evaluations for the circumferential measurements would eliminate the variability in results. Some form of formal tracking of attendance at the fitness centers should be used to decrease reliance of subjective reporting of participants. Future research regarding these two fitness programs is needed as this is the first study comparing hydraulic circuit training and mat Pilates.

Clinical Implications

From the trends that were found, there are benefits from exercise especially when beginning a new program. Both of these programs could be completed in 30-45 minutes making it a time efficient exercise regime. Due to the minimal time requirements for exercising, these two forms of exercise can provide women with an efficient program without taking away from their social roles as mother and wife.

Prevention and wellness have become increasing aspects in physical therapy practice. From the trends seen in this study, these two forms of exercise along with a

balanced diet could help provide a strategy for effective and efficient overall health for women. Improving overall health will aid in decreasing the risks of diabetes, cardiovascular disease and obesity. Physical therapists can be directly involved in this aspect as they are providers of exercise prescriptions regarding frequency, intensity, type of exercises performed, duration of the workout, proper techniques and individualized exercises based on patient's needs.

Conclusion

The results from this study show there are no significant differences between the hydraulic circuit training and Pilates groups. Trends, however, were seen in each group that shows the benefits of physical activity. Future studies in this area would be beneficial especially with longer follow-up periods to see the effects of exercise over a longer period of time.

APPENDIX A

University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below:

Principal Investigator: Sandra L. Hoff, Shauna L Differding, Sara L. Murray

Telephone: 701-840-2925 E-mail Address: shoff@medicine.nodak.edu

Complete Mailing Address: 2917 S 17th St. Apt. #303 Grand Forks, ND 58201

School/College: University of North Dakota Department: Physical Therapy

Student Adviser (if applicable): Michelle LaBrecque

Telephone: 701-777-2831 E-mail Address: mlabrecq@medicine.nodak.edu

Address or Box #: P.O. Box 9037 501 N Columbia Rd Grand Forks, ND 58203

School/College: University of North Dakota Department: Physical Therapy

Project Title: Comparison of Pilates and Hydraulic Circuit Training in Women

Proposed Project Dates: Beginning Date: July 17, 2006 Completion Date: Dec 22, 2006
(Including data analysis)

Funding agencies supporting this research: N/A

Did the contract with the funding entity go through UND Grants and Contracts Administration? ☐ YES or ☒ NO
Attach a copy of the contact. Do not include the any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

☐ YES or ☒ NO Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

☒ YES or ☐ NO Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?

If yes, list all institutions: Center Court Fitness Club, Altru Health Systems, Curves

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on letterhead.

Does any external site where the research will be conducted have its own IRB? ☒ YES ☐ NO ☐ N/A

If yes, does the external site plan to rely on UND's IRB for approval of this study? ☐ YES ☒ NO ☐ N/A
(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

Altru IRB Date submitted: 09/26/06 Status: ☒ Approved ☐ Pending

Date submitted: _____ Status: ☐ Approved ☐ Pending

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

Type of Project: Check "Yes" or "No" for each of the following.

☐ YES or ☒ NO New Project

☐ YES or ☒ NO Continuation/Renewal

☐ YES or ☒ NO Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.

☐ YES or ☒ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

☐ YES or ☒ NO Does your project include Genetic Research?

☐ YES or ☒ NO Does your project include Internet Research?

☐ YES or ☒ NO Dissertation/Thesis/Independent Study

☒ YES or ☐ NO Student Research Project

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

☐ Children (< 18 years)
☐ Prisoners
☐ Persons with impaired ability to understand their involvement and/or consequences of participation in this research
☒ Other Women
☐ UND Students
☐ Pregnant Women/Fetuses

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

This study will involve: Check all that apply.

☐ Deception (Attach Waiver or Alteration of Informed Consent Requirements)
☐ Radiation
☐ New Drugs (IND) IND # _____Attach Approval
☐ Investigational Device Exemption (IDE) # _____Attach Approval
☐ Non-approved Use of Drug(s)
☒ None of the above will be involved in this study
☐ Stem Cells
☐ Discarded Tissue
☐ Fetal Tissue
☐ Human Blood or Fluids
☐ Other _____

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

This study is designed to find a safe and effective fitness program for women in areas of flexibility, strength, circumferential measurements, vitals and personal satisfaction. The fitness programs included in this study will include mat Pilates and hydraulic circuit training. This study will add to the limited research regarding these two forms of exercise. It will provide women information about results and efficient fitness programs. All subjects will include the special population of only women. Women only will be allowed to participate in this study because Curves, which specializes in hydraulic circuit training, is exclusively designed for women.

II. Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.

a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.

All research investigators will recruit participants with the help of local facilities (Center Court Fitness Club, Altru Health Systems, and Curves). Poster will be displayed at each of the facilities which will include a brief description of the study, sign-up sheet and investigators names and contact information. The sign-up sheet for those interested will be located in a non-see-through folder behind the front desk which will not be visible to the public. Individuals who have access to this

folder will be the staff of the respective facilities and the research investigators. When an individual signs up for the study, they will leave their name and number so the research investigators can contact them. Individuals who may have any concerns or questions prior to signing up for the study may contact one of the research investigators by using the numbers listed on the flier. Participants will be recruited upon approval from IRB through November 1st, 2006. Recruitment will be done at eh above facilities. An incentive will be offered to the Pilates group and Curves group, consisting of one free month of membership as either Curves, Center Court Fitness or Altru Fitness Center depending on which group they are enrolled in. All participants will be entered into a drawing for the free month memberships. There will be only one winner for each group.

b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.

Subject selection procedures include posting fliers at each facility to inform individuals of the study. Research investigators contact information will be available for further information or to answer any questions. Participants will volunteer to be a part of this study and will be divided into mat Pilates or hydraulic circuit training groups. Subject inclusion criteria will be women 18 years and older, beginners (have not participated in chosen program for the past year), cardiovascular function within normal limits (heart rate 60-100, blood pressure <140/<90, self-reported past medical history), light to moderate activity (30-45 minutes less than 3 times per week, including other formal training), and decision to begin program of choice prior to start of the study. Curves serves only women and therefore only women will be used for mat Pilates to keep baseline characteristics similar.

c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

Exclusion criteria include men, pregnant women, current training for collegiate athletics, history of cardiovascular disease, persons with impaired ability to understand their involvement, minors and prisoners. Men are excluded from the study because they are unable to participate at Curves. Pregnant women are excluded because of the changes their body will incur from the pregnancy which would affect the results of this study. People who are currently training for collegiate athletics are excluded because they will not meet the criteria of light to moderate activity. Due to safety concerns, people with a self-reported history of cardiovascular disease or values outside of listed norms are excluded.

d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

The estimate number of participants will be up to 60 with goals of up to 30 participants for mat Pilates and hydraulic circuit training.

e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

The potential for valid results of this study is fair to good because of the inclusion and exclusion criteria set, goal of 60 total participants, and intra-rater reliability of research investigators. Each investigator will be performing a specific measurement for all participants throughout the whole study.

2. Description of Methodology.

a) Describe the procedures used to obtain informed consent.

Each participant will be given an informed consent sheet to sign before they are able to participate in this research study.

b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

The research will be conducted at the respective facilities. There will be allotted times of one hour, two days a week at each facility in order to gather information and data. All measurements will be taken in a private room to ensure participant modesty and confidentiality. All instruments including microfet, tape measure, sit-and-reach box, stethoscope and blood pressure cuff will be provided by the Univeristy of North Dakota Physical Therapy Department.

c) Indicate who will carry out the research procedures.

All research investigators will be conducting this study. Each investigator will be conducting certain measurements throughout the entire study to increase reliability of measurements.

d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

Prior to being allowed to participate in the study, a short initial intake form will be given to the individual to determine if they meet the inclusion/exclusion criteria. Some of the information on the intake form includes past medical history information and family history. No information is taken from medical records, only information given from patient to answer the intake form questions. The areas being assessed include flexibility, strength, and circumferential measurements. Flexibility will be measured using the sit-and-reach technique which consists of participant sitting on the floor with knees straight and feet up against the box. A yardstick is attached to the top of the box, the participant places one hand on top of the other, and on the count of three reaches forward as far as possible while keeping knees straight and holds 3 seconds without bouncing. A measurement is then taken by looking at where the fingers reach on the ruler. Three measurements will be taken and averaged for each participant. Strength will be measured with a Microfet stabilized on an adjustable metal bar. The Microfet is hand-held instrument that measures strength using pounds and it electronically records the amount of resistance applied to the device. The device will be stabilized on an adjustable metal bar to reduce variability. The participant would push into the Microfet with maximum strength in each of the following locations. The area to be assessed will be elbow flexion with Microfet placed on anterior forearm at the distal wrist crease with the elbow at 90 degrees of flexion. The second area to be assessed will be knee extension with Microfet placed on the anterior lower leg 3 cm proximal to the inferior aspect of the medial malleolus and the knee at 45 degrees of flexion. Depending on the individual it may be possible to get a bruise due to the pressure of the Microfet. Measurements will be taken bilaterally and an average of three tests per spot will be used. Sit-ups will be timed for 30 seconds, and the number of sit-ups will be counted during this time. Circumferential measurements will be taken at fullest part of bust, top of iliac crests, greater trochanters, and fullest part of upper thigh. Each participant will be measured at various places on the upper thigh to find the fullest part and once the fullest area has been found, this distance from the anterior superior iliac spine will be measured and documented for each participant for more consistent readings. Vital signs will be taken in a sitting position and taken before any of the other measurements have been taken. The vital signs which will be measured include blood pressure and resting heart rate. The Short-Form 36 questionnaire regarding quality of life will be given prior to the start of the fitness program. All above measurements/questionnaire will be taken again after 6 weeks of participation in fitness program.

e) Describe audio/visual procedures and proper disposal of tapes.

There will be no audio or visual procedures used in this study.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

All research investigators are students of the University of North Dakota Doctor of Physical Therapy program. All techniques used for gathering data has been practiced in the classroom under instructor supervision and students are competent in these areas.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).

There will be no compensation for being a participant in this research project.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

3. Risk Identification.

a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

There are no perceived financial risks from participating in this study. Possible physical risks may include hematoma due to Microfet pressure, muscle soreness from overexertion on Microfet, pinching during circumferential measurement, and hamstring soreness from overexertion during sit-and-reach. In the event that this research activity results in a physical injury, medical treatment will be as available as it is to a member of the general public in similar circumstances. Participants and their third party payors must provide payment for any such treatment. The researchers and the University

of North Dakota will not be held liable for any injuries. Possible emotional risks include dissatisfaction of initial measurements and final measurements as well as disappointment of end results.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

There will be no link between subject responses or data to consent form. All information will be kept confidential.

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

To limit the potential risks to the participants, research investigators will explain all procedures and techniques in detail before having the participants perform them. Demonstrations will be done at the initial assessment to show proper form when using the sit-and-reach and Microfet to prevent potential injury. Sterilization of equipment by wiping it with an alcohol as well as proper hand washing techniques between subjects will be performed by the research investigators to minimize the risk of spreading micro-organisms.

b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

When the participant signs the informed consent, there will be a reference number code associated with each form. Signed informed consent forms will be stored separately from the data in locked cabinets to ensure confidentiality. The separate locked cabinets are located on the second floor of the UND physical therapy department.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

Each participant will be provided a copy of the consent form.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study. Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed

Information that is obtained by the researchers in connection with this study and that can be identified with the participants name will remain confidential and will be disclosed only with their permission. A number known only to the investigators will be identified with the data. The only persons with access to this data are the researchers, statistician, and individuals who are authorized to examine those procedures (Institutional Review Board auditors). For a length of three years, this consent form and the data associated with it will be kept in different locked cabinets. After three years have passed, they will be destroyed by shredding all information.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

No adverse reactions are anticipated with procedures this study requires.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

In the event that this research activity results in a physical injury, medical treatment will be as available as it is to a member of the general public in similar circumstances. Participants and their third party payors must provide payment for any such treatment. The researchers and the University of North Dakota will not be held liable for any injuries.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

The benefits to the participants include seeing the results of starting a fitness program. Society will benefit from this study because it will show which of these two up-and-coming fitness programs have the potential to produce consistent results for women. Due to the limited current literature, other research regarding these two fitness programs could be conducted to follow-up this study.

IV. Consent Form

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. **Please note:** All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. **The consent form should be written at no higher than an 8th grade reading level**, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

(Principal Investigator) Date:

(Student Adviser) Date:

Requirements for submitting proposals:
Additional information can be found on the IRB web site at **www.und.nodak.edu/dept/orpd/regucomm/IRB/index.html.**

Original Proposals and all attachments should be submitted to Research Development and Compliance, P.O. Box 7134, Grand Forks, ND 58202-7134, or brought to Room 105, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to http:// http://www.und.edu/dept/rdc/regucomm/IRB/IRBEducation.htm for more information.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the RD&C website regarding required copies and IRB review categories, or you may call the RD&C office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

Please note: All Researchers must complete the "Investigator Letter of Assurance of Compliance" and submit it along with this form. All Student Researchers must also complete the "Student Consent to Release of Educational Record".

INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS

I _____
(Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)

2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.

3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

_____ _____
Investigator Signature Date

STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD[1]

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is _____

_____

_____.

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

_____ _____

NAID # Printed Name

_____ _____

Date Signature of Student Researcher

[1]Consent required by 20 U.S.C. 1232g.

APPENDIX B

Altru Health System

Revised 3/24/05

Institutional Review Board
Human Subjects Review Form

For new projects or procedural revisions to approved projects involving human subjects.

Date: October 10, 2006 IRB # ST-24

Principal Investigator: Sandra Hoff, Sara Murray, Shauna Differding Phone # (701)840-2925

Address to which notice of approval should be sent: 2917 S 17th St Apt 303 Grand Forks, ND 58201

Institution: University of North Dakota Department: Physical Therapy

Research Coordinator(s): Michelle LaBrecque Phone # (701)777-2831

Proposed Project Dates: October 3, 2006 –December 15, 2006

E-mail address: shoff@medicine.nodak.edu

Project Title: Comparison of Pilates and Hydraulic Circuit Training in Women

Funding Agencies (if applicable): N/A

Type of Project: ☒ New Project θ Continuation θ Renewal
☒ Student Research Project θ Dissertation or Thesis Research

Reports: θ Administrative Change θ Protocol Revision θ Revised Consent Form
θ Amendments or Change in Project θ Adverse Event θ Other

Dissertation/Thesis Advisor, or Student Advisor: Michelle LaBrecque

Proposed Project: θ Involves New Drugs (IND) θ Involves Non-Approved Use of Drug
θ Involves a Cooperating Institute ☒ None of the Above

If any of your subjects fall in any of the following classifications, please indicate the classification:
θ Minors (< 18 years) θ Pregnant Women θ Mentally Disabled θ Fetuses θ Mentally Retarded
θ Prisoners θ Students θ Abortuses θ Control Group

If your project involves any human tissue, body fluids, pathological specimens, donated organs, fetal material, or placental materials, check here: θ

☒ Expedited Review requested under item 4+7 (number) of HHS Regulations (see attached explanation)
θ Exempt Review requested under item _____ (number) of HHS Regulations (see attached explanation)

If your project has been/will be submitted to another Institutional Review Board(s), please list name of Board(s): **If you affiliated to UND we will need an extra copy of your proposal.**

University of North Dakota

Status of submission to another IRB: θ Submitted: date_____; ☒ Approved: date August 29, 2006;

θ Pending

Any additional information should be documented on a separate sheet of paper.

Last updated 3/24/05 *Completed by:*_____

1. ABSTRACT (Limit to 200 words or less and include justification or necessity for using human subjects. Attach additional sheet if necessary.)

This study is designed to find a safe and effective fitness program for women in areas of flexibility, strength, circumferential measurements, vitals and personal satisfaction. The fitness programs included in this study will include mat Pilates and hydraulic circuit training. This study will add to the limited research regarding these two forms of exercise. It will provide women information about results and efficient fitness programs. All subjects will include the special population of only women. Women only will be allowed to participate in this study because Curves, which specializes in hydraulic circuit training, is exclusively designed for women.

PLEASE NOTE:

Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal including data collection instruments where applicable.

2. PROTOCOL: (Describe procedures to which humans will be subjected.)

Prior to being allowed to participate in the study, a short initial intake form will be given to the individual to determine if they meet the inclusion/exclusion criteria. Some of the information on the intake form includes past medical history information and family history. No information is taken from medical records, only information given from patient to answer the intake form questions. The areas being assessed include flexibility, strength, and circumferential measurements. Flexibility will be measured using the sit-and-reach technique which consists of participant sitting on the floor with knees straight and feet up against the box. A yardstick is attached to the top of the box, the participant places one hand on top of the other, and on the count of three reaches forward as far as possible while keeping knees straight and holds 3 seconds without bouncing. A measurement is then taken by looking at where the fingers reach on the ruler. Three measurements will be taken and averaged for each participant. Strength will be measured with a mircofet stabilized on an adjustable metal bar. The microfet is a hand-held instrument that measures strength using pounds and it electronically records the amount of resistance applied to the device. The device will be stabilized on an adjustable metal bar to reduce variability. The participant would push into the microfet with maximum strength in each of the following locations. One area to be assessed will be elbow flexion with the microfet placed on anterior forearm at the distal wrist crease with the elbow at 90 degrees of flexion. The second area to be assessed will be knee extension with the microfet placed on the anterior lower leg 3 cm proximal to the inferior aspect of the medial malleolus and the knee at 45 degrees of flexion. Depending on the individual it may be possible to get a bruise due to the pressure of the microfet. Measurements will be taken bilaterally and an average of three tests per spot will be used. Sit-ups will be timed for 30 seconds, and the number of sit-ups will be counted during this time. Circumferential measurements will be taken at fullest part of bust, top of iliac crests, greater trochanters, and fullest part of upper thigh. Each participant will be measured at various places on the upper thigh to find the fullest part and once the fullest area has been found, this distance from the anterior superior iliac spine will be measured and documented for each participant for more consistent readings. Vital signs will be taken in a sitting position and taken before any of the other measurements have been taken. The vital signs which will be measured include blood pressure and resting heart rate. The Short-Form 36 questionnaire regarding quality of life will be given prior to the start of the fitness program. All above measurements/questionnaire will be taken again after 6 weeks of participation in fitness program.

3. BENEFITS: (Describe the benefits to the individual or society)

The benefits to the participants include seeing the results of starting a fitness program. Society will benefit from this study because it will show which of these two up-and-coming fitness programs have the potential to produce consistent results for women. Due to the limited current literature, other research regarding these two fitness programs could be conducted to follow-up this study.

4. RISKS: (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

There are no perceived financial risks from participating in this study. Possible physical risks may include hematoma due to microfet pressure, muscle soreness from overexertion on microfet, pinching during circumferential measurement, and hamstring soreness from overexertion during sit-and-reach. In the event that this research activity results in a physical injury, medical treatment will be as available as it is to a member of the general public in similar circumstances. Participants and their third party payors must provide payment for any such treatment. The researchers and the University of North Dakota have no plans to compensate individuals for any injuries which may occur. Possible emotional risks include dissatisfaction of initial measurements and final measurements as well as disappointment of end results.

5. **CONSENT FORM:** A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe who will be obtaining consent, where signed consent forms will be kept, and for what period of time.

When the participant signs the informed consent, there will be a reference number code associated with each form. Signed informed consent forms will be stored separately from the data in locked cabinets to ensure confidentiality. The separate locked cabinets are located on the second floor of the UND physical therapy department. These documents will be kept for three years following completion of the project.

6. For **FULL IRB REVIEW**, forward the signed original and 14 copies of this completed form and, when applicable, 14 copies of the proposed consent form, questionnaires, etc., and any supporting documentation to:

For **EXEMPT or EXPEDITED REVIEW**, forward a signed original and a copy of the consent form, questionnaires, etc., and any supporting documentation to:

Marie-Laure Reese - IRB Associate
Altru Hospital – 6th floor
1200 South Columbia Road/PO Box 6002
Grand Forks ND 58206-6002
(Telephone 701-780-6161)

****
****

The policies and procedures on Use of Human Subjects in Altru Health System Institutions apply to all activities involving use of Human Subjects performed by personnel conducting such activities. No activities are to be initiated without prior review and approval of the Altru Health System Institutional Review Board.

Signatures:

Principal Investigator: Sara Murray, Shawna Dykstra Date: 10.10.2006

Project Director: _____ Date: _____

Research Coordinator: _____ Date: _____

Student Advisor (where applicable): Michelle LaBrecque Date: 10/10/06

APPENDIX C

Reference Number:_____

Information and Consent Form

Title of Study: Comparison of Pilates and Hydraulic Circuit Training in Women

Principal Investigators: Shauna Differding, SPT, Sandy Hoff, SPT, Sara Murray, SPT, and Michelle LaBrecque, PT, DPT from the Department of Physical Therapy at the University of North Dakota

You are being asked to participate in this study of comparing results regarding flexibility, strength, circumferential measurements, vitals and personal satisfaction between mat Pilates and hydraulic circuit training. The purpose of this study is to find an effective fitness program for women based on the above criteria. This study will add to the limited research and help determine if either fitness program is successful in order to refer women for overall fitness, and which is more beneficial to the individual.

You were chosen because: 1) you are a healthy woman over the age of 18 years, 2) are a beginner participating in either program, 3) are not pregnant, 4) participate in moderate activity of 30-45 minutes no more than 3 times per week, 5) are not training for collegiate athletics, and 6) have no current or previous history of cardiovascular disease.

As a subject in this study, you will be evaluated at the respective facility of your fitness program. The evaluation will take place initially within the first week of starting your fitness program and will take approximately 30 minutes of your time. An initial medical intake form will be filled out by you and investigators will take heart rate and blood pressure measurements (vital signs) while seated. A second evaluation will be done after 6 weeks of participating in the fitness program. The five measurements recorded at both evaluations are flexibility, strength, circumferential measurements, vitals and short-form 36 quality of life questionnaire. Flexibility will be measured by assessing hamstring flexibility using the sit-and-reach technique. Strength will be assessed at the elbow, knee and abdominals using a microfet, which is a small hand-held instrument that records strength electronically when pressure or resistance is given, and number of sit-ups done in 30 seconds. Circumferential measurements will be assessed with a tape measure at the fullest part of the bust, waist, hips, and upper thigh. For all of the above, an average of three measurements for each test will be taken and recorded with the exception of circumferential measurements, sit-ups and vital signs.

The risk of injury to you as a subject is relatively minimal. Possible physical risks may include bruising due to microfet pressure, muscle soreness from overexertion on

microfet, pinching during circumferential measurement, and hamstring soreness from overexertion during sit-and-reach. Possible emotional risks include dissatisfaction of initial measurements and final measurements as well as disappointment of end results. In the event that this research activity results in a physical injury, medical treatment will be as available as it is to a member of the general public in similar circumstances. You and your third party payor must provide payment for any such treatment. UND, UND Physical Therapy Department faculty or staff, and the researchers of this study will not be held liable for any injury sustained during this study.

All Curves participants will be entered into a drawing for a one month free membership to Curves. All Pilates participants will be entered into a drawing for a one month free membership to either Center Court Fitness or Altru Fitness Center depending on respective facility of enrollment. You will be provided with information from the initial and final evaluations regarding measurements if requested.

In any reports of this study, your name will not be used. Information that is obtained by the researchers in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. A number known only to the investigators will be identified with the data. The only persons with access to this data are the researchers, statistician, and individuals who are authorized to examine those procedures (Institutional Review Board auditors). For a length of three years, this consent form and the data associated with it will be kept in different locked cabinets in UND Department of Physical Therapy. After three years following completion of this study have passed, they will be destroyed appropriately by shredding all documents.

You or the researchers may stop the experiment at any time if you are experiencing any type of pain, discomfort, fatigue or other symptoms that may be harmful to your health. You have the right to participate, as it is voluntary and your decision to end your participation in this study will not discriminate your future relationship with the Physical Therapy Department at the University of North Dakota. If you do participate, you have the right to discontinue at any time without prejudice/penalty.

The researchers involved in this study are here to answer any questions you have in regards to this study. One of the three researchers will sign as a witness in order to make sure this consent form was signed properly and verify all questions have been answered prior to signing this form. You are also encouraged to ask any questions concerning this study that you may have in the future. In the event you do have questions, you may call Shauna Differding at (701) 840-2852, Sandy Hoff at (701) 840-2925, Sara

Murray at (701) 740-0663 or Michelle LaBrecque at (701) 777-2831. Any further questions or concerns can be directed towards the Office of Research and Program Development at (701) 777-4279. In addition, you will be given a copy of this form for future reference.

All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future. I have read all of the above information and willingly agree to participate in this study as it is explained to me by Shauna Differding, Sandy Hoff and/or Sara Murray. My signature indicates I have read the above information and agree to participate in this study.

_____

Subject's Printed Name

_____

Subject's Signature **Date**

_____

Witness' Signature Date

Reference Number:_____

INFORMATION AND CONSENT FORM

Title of Study: Comparison of Pilates and Hydraulic Circuit Training in Women

Principal Investigators: Shauna Differding, SPT, Sandy Hoff, SPT, Sara Murray, SPT, and Michelle LaBrecque, PT, DPT from the Department of Physical Therapy at the University of North Dakota

You are being asked to participate in this study of comparing results regarding flexibility, strength, circumferential measurements, vitals and personal satisfaction between mat Pilates and hydraulic circuit training. The purpose of this study is to find an effective fitness program for women based on the above criteria. This study will add to the limited research and help determine if either fitness program is successful in order to refer women for overall fitness, and which is more beneficial to the individual.

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As a subject in this study, you will be evaluated at the respective facility of your fitness program. The evaluation will take place initially within the first week of starting your fitness program and will take approximately 30 minutes of your time. An initial medical intake form will be filled out by you and investigators will take heart rate and blood pressure measurements (vital signs) while seated. A second evaluation will be done after 6 weeks of participating in the fitness program. The five measurements recorded at both evaluations are flexibility, strength, circumferential measurements, vitals and short-form 36 quality of life questionnaire. Flexibility will be measured by assessing hamstring flexibility using the sit-and-reach technique. Strength will be assessed at the elbow, knee and abdominals using a microfet, which is a small hand-held instrument that records strength electronically when pressure or resistance is given, and number of sit-ups done in 30 seconds. Circumferential measurements will be assessed with a tape measure at the fullest part of the bust, waist, hips, and upper thigh. For all of the above, an average of three measurements for each test will be taken and recorded with the exception of circumferential measurements, sit-ups and vital signs.

The risk of injury to you as a subject is relatively minimal. Possible physical risks may include bruising due to microfet pressure, muscle soreness from overexertion on

microfet, pinching during circumferential measurement, and hamstring soreness from overexertion during sit-and-reach. Possible emotional risks include dissatisfaction of initial measurements and final measurements as well as disappointment of end results. In the event that this research activity results in a physical injury, medical treatment will be as available as it is to a member of the general public in similar circumstances. You and your third-party payor must provide payment for any such treatment. UND, UND Physical Therapy Department faculty or staff, and the researchers of this study have no plans to compensate individuals for an injury which may occur.

All Pilates participants will be entered into a drawing for a one month membership to Center Court Fitness or Altru. You will be provided with information from the initial and final evaluations regarding measurements if requested.

In any reports of this study, your name will not be used. Information that is obtained by the researchers in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. A number known only to the investigators will be identified with the data. The only persons with access to this data are the researchers, statistician, and individuals who are authorized to examine those procedures (Institutional Review Board auditors). For a length of three years, this consent form and the data associated with it will be kept in different locked cabinets in UND Department of Physical Therapy. After three years following completion of this study have passed, they will be destroyed appropriately by shredding all documents.

You or the researchers may stop the experiment at any time if you are experiencing any type of pain, discomfort, fatigue or other symptoms that may be harmful to your health. You have the right to participate, as it is voluntary and your decision to end your participation in this study will not discriminate your future relationship with the Physical Therapy Department at the University of North Dakota. If you do participate, you have the right to discontinue at any time without prejudice/penalty.

The researchers involved in this study are here to answer any questions you have in regards to this study. You are also encouraged to ask any questions concerning this study that you may have in the future. In the event you do have questions, you may call Shauna Differding at (701) 840-2852, Sandy Hoff at (701) 840-2925, Sara Murray at (701) 740-0663 or Michelle LaBrecque at (701) 777-2831. Any further questions or concerns can be directed towards the Office of Research and Program Development at (701) 777-4279. In addition, you will be given a copy of this form for future reference.

All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future. I have read all of the above information and willingly agree to participate in this study as it is explained to me by Shauna Differding, Sandy Hoff and/or Sara Murray. My signature indicates I have read the above information and agree to participate in this study.

_____
Subject's Printed Name

_____
Subject's Signature Date

_____
Witness' Signature Date

APPENDIX D

Initial Intake Form

Reference Number:
Date:

Pregnant: Yes or No

Currently training for collegiate athletics: Yes or No

How many days per week do you engage in moderate activity for 30-45 minutes?_____
This includes leisure activities or formal exercise program

Have you done this fitness program before: Yes or No
If yes, when was last time you participated?

Family History of heart disease (Relationship and diagnosis): _____

_____

Current and/or past medical history of heart disease:_____

Investigators will fill out below this line_____

Initial Measurements:	**Final Measurements:**
Strength:	Strength:
Flexibility:	Flexibility:
Circumferential:	Circumferential:
SF-36:	SF-36:
Blood Pressure:	Blood Pressure:
Heart Rate:	Heart Rate:

References

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