

Special Issue on ASEAN Meta-Analytic Reviews on Health & Exercise Science

ASEAN Scholarly Researches on Health & Exercise Science

This special issue was conceived to provide a platform to disseminate outcomes of researches conducted in ASEAN Universities, employing cutting-edge technologies to investigate on intricate and yet unexplored aspects associated with enhancement in sport performance excellence, and factors associated with management of health risk factors as well. Meta-analytic systematic review studies were included, which examined impacts of exercise and behavioural interventions in reducing the level of HbA1c among Malaysian Type 2 Diabetes Mellitus patients. Apart from that, effects of conventional physiotherapy exercise training regimes in enhancing muscle strength and in reduction of pain among female osteoarthritis patients were also investigated.

Experimental researches included in this special issue, investigated on effectiveness as well as cost-effectiveness of differential exercise intervention programs on improvement in perceived health-status evident among Malaysian diabetic individuals. Differential impacts of isokinetic training and conventional physiotherapeutic exercise intervention on perceived discomfort and pain in osteoarthritis patients was also investigated. Further to that, randomised controlled trials incorporating impacts of isokinetic training regimes, which were introduced following rigorous methodology, were also included in this issue, which investigated extents of improvement in pain management. Further to that, in-depth analyses on facilitative effects of isokinetic training on improvement of proprioception (reduction of active repositioning error) and on increment in peak torque generation were also carried out, which explained intricate processes involved in pain management among osteoarthritic patients of Malaysia.

Psychotherapeutic advancements in modulating performance, were also included in this special issue. These experimental trials by virtue of randomization studies investigated on the causal association between psychological and psychobiological interventions introduced in differential regimes, and the resultant impacts on performance excellence of sport skills.

Impact of emotionality, mood and autonomic factors, and impacts of differential biofeedback interventions on mood and emotional regulation, and also impact of autonomic competence and mood factors on reaction performance and other psychomotor abilities were investigated. Furthermore, enhancement in soccer agility, juggling skills and also bilateral shooting performance evident among promising Malaysian soccer players were investigated. Apart from Malaysian participants, researches on Indonesian athletes were also included, which on the basis of structural models revealed significance of concentration, self-confidence and emotional regulation among promising sprinters. Further to all these, empirical evidences on impacts of nutritional supplementation (different dosage of sodium bicarbonate) on freestyle swimming performance evident among Malaysian competitive swimmers was also investigated.

All these researches were critically reviewed and evaluated on the basis of double-blind review and based on suggestions optimal modifications of the original research submissions were adequately ensured. As Guest-editors of this issue, no stone was left unturned by us to warrant quality and validity of the researches, although core integrity of the academic discipline in concern was always upheld. We can vouchsafe that our aspiring attempts were only to contribute to the academic and research milieu of ASEAN communities, in order to encourage further replicated studies enriching the prevailing notions on exercise and health science studies in these regions. Here I am being the Lead Guest-Editor, would like to acknowledge the dedication of all the Guest -Editors and Reviewers, and I would most sincerely like to thank all of them, who relentlessly took care of their responsibilities to ensure validity of the researches and high academic standard of this issue.

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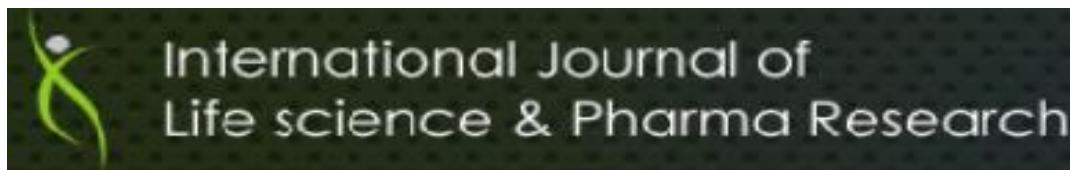
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EFFECTS OF CONVENTIONAL PHYSIOTHERAPY IN REDUCTION OF PAIN IN FEMALE OSTEOARTHRITIS PATIENTS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

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This review was carried out to find out the effectiveness of conventional physiotherapeutic (CP) training on reduction of pain in middle-aged and elderly female individuals diagnosed as having Osteoarthritis (OA) of knee. Multiple databases having articles published between 2000 and 2016, such as - Web of Science, ProQuest, PubMed, Ebscohost and CINAHL were methodically searched for articles related to OA of knee. Only descriptive, meta-analytical and interventional research articles were retained. Overall effect size with 95% confidence intervals (CIs) was used to assess the strength of the relationship between interventions and reduction of pain among elderly OA of knee patients, by using a random effects model. Heterogeneity was also evaluated. 20 experimental studies were selected and included in the review, out of which 8 were randomized controlled trials and rest were pseudo-randomised controlled trials. Studies considering drug co-interventions were excluded. Standardized effect sizes with 95% confidence interval (CIs) were calculated from the pre-intervention and post-intervention means of the conventional physiotherapy (CP) training group and other intervention or no-intervention group. Altogether twenty articles were analysed for reduction of pain. Pooled analysis of the results from the articles included clarified that, out of twenty articles, fifteen studies favoured CP training as a modality for reduction of pain in elderly OA patients. Rest of the articles (five articles) were found to favour no-intervention condition. This study confirmed the effectiveness of conventional physiotherapeutic (CP) training in reducing pain in OA patients.

KEYWORDS: *Osteoarthritis, Conventional physiotherapy training, Pain, Meta-analysis*

1. INTRODUCTION

Modern hectic and inconsistent life-style being coupled with extreme aspirations for unachievable targets, results in several crises

leading to overuse syndrome disorders, such as osteoarthritis. Osteoarthritis (OA), especially in knees relates to destruction of cartilage and damage of the subchondral bone. The prevalence of osteoarthritis has been on the rise due to

increase in the elderly population. Physiotherapeutic interventions have been documented in improving muscle strength, reducing pain and in enhancing physical functionality in elderly individuals diagnosed as having OA of knee.¹⁻² Conventional physiotherapy exercise treatment is one of such non-pharmacological treatments intervention³, comprised of exercise regimes such as strengthening exercise, stretching exercise and range of motion exercise are included in the treatment of participants with knee OA.⁴

In the process of rehabilitation for the knee osteoarthritis patients, impacts of different physiotherapy-oriented exercise forms have been identified, which could be tailored for knee OA patients in improving physical function, enhancing range of motion (ROM) of knee joint and in reducing pain. These studies have carried out in-depth analysis to find out the most effective protocols to treat the knee OA participants.^{1,5-9} This section of review illustrates the impact of different Conventional Physiotherapy (CP) exercise regimes in reducing pain in the knee OA participants.

Although, lots of studies have been conducted to evaluate the effectiveness of physiotherapy protocols on OA of knee, but introduction of CP exercises on knee OA patients and impact of those training regimes in reducing perceived pain of OA patients have so far not been

accounted for. This study based on meta-analytical systematic review of reported literatures, intends to evaluate impact of CP in reducing pain among middle-aged and elderly individuals diagnosed as suffering from OA of knee.

2. META-ANALYSIS ON THE OUTCOME OF CONVENTIONAL PHYSIOTHERAPY IN KNEE OA

A meta-analysis has been carried out to assess the impact of Conventional Physiotherapy in knee OA. Explanations on Meta-analysis process has been discussed below.

2.1 Search Strategy

Existing published literature (2000 to 2016) and online sites such as Web of Science, ProQuest, PubMed, Ebscohost and CINAHL were thoroughly searched for this analysis. The terms such Conventional Physiotherapy OR physiotherapeutic exercises OR Conventional Physiotherapy in knee osteoarthritis OR physiotherapy in knee osteoarthritis OR exercise in knee osteoarthritis have been used in search strategy (Table 1). Cross-referencing was also done to find out articles related to this review. Selection process for the articles has been depicted by the PRISMA flow diagram (Figure 1).

Table 1
Search Strategy

Databases	Search Items
Web of Science, ProQuest, PubMed, Ebscohost and CINAHL	The following terms as words within the title, abstracts or text of research literatures: “Physiotherapy”, “exercises”, “osteoarthritis”, “knee osteoarthritis” and “exercise in knee osteoarthritis”. “Conventional Physiotherapy”, “physiotherapeutic exercises”, “Conventional Physiotherapy in knee osteoarthritis”, “physiotherapy in knee osteoarthritis” and “exercise in knee osteoarthritis” as words within the title, abstracts or texts of papers.

2.2 Inclusion Criteria:

The criteria for the study to be included in the review as follow:

- Studies included Conventional Physiotherapy to treat participants with knee OA.
- Only Conventional Physiotherapy and a comparative exercise and / or any other

intervention to reduce pain in participants diagnosed as having knee OA.

- Participants with knee OA.
- Included studies were required to assess the changes in pain.
- Articles published between 2000 to 2016 and in English language were taken into account.

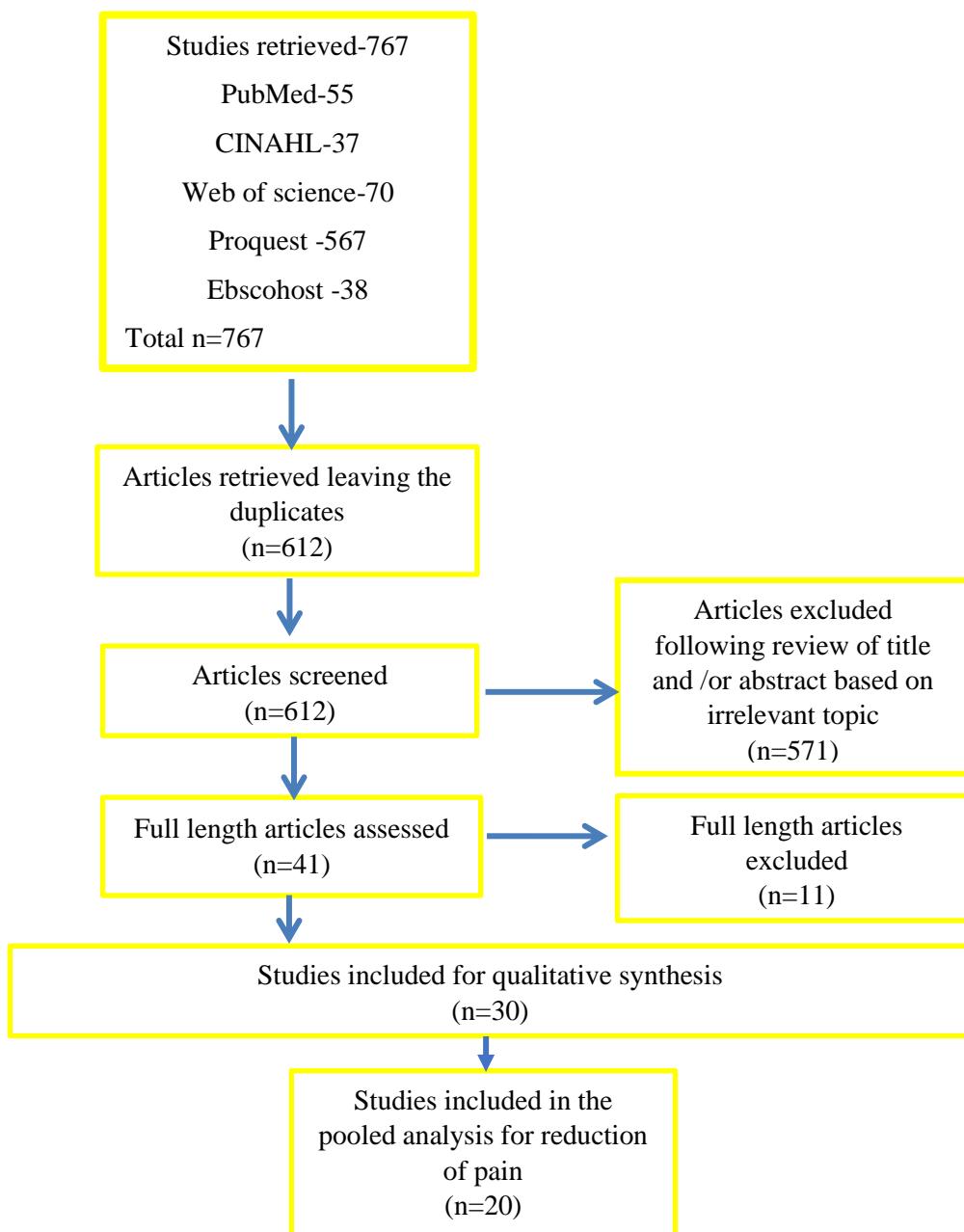


Figure 1
PRISMA Flow Diagram

2.3 Methodological Quality Assessment:

Physiotherapy Evidence Database (PEDro) scale has been used to assess the methodological quality of all the articles that were included in this review.

This is a widely used tool to evaluate the methodology of the studies and it consists of 11 – point scale. The PEDro scores are shown below (Table 2).

Table 2
PEDro Scores of the Trials

Study	1. Eligibility criteria?	2. Random allocation?	3. Concealed allocation?	4. Baseline Similarity?	5. Blind participants?	6. Blinding therapists?	7. Blinding assessors?	8. Follow up?	9. Intention to treat analysis?	10. Group comparison?	11. Point and variability?	Score
Shyam et al., 2015	✓	✓	x	✓	x	x	x	x	✓	✓	x	5/11
Anwer et al., 2014	✓	✓	x	✓	x	✓	x	x	✓	✓	x	6/11
Ju et al., 2015	✓	✓	x	✓	x	x	x	x	✓	✓	x	5/11
Swank et al., 2011	✓	✓	x	✓	x	x	x	x	✓	✓	✓	6/11
Kumar et al., 2013	✓	✓	✓	✓	✓	x	x	x	✓	✓	x	7/11
Gul et al., 2015	✓	✓	✓	✓	✓	x	x	x	✓	✓	x	7/11
Jebakani et al., 2015	x	✓	x	✓	x	x	x	x	✓	✓	✓	5/11
Knoop et al., 2013	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11/11
Tiwari, 2015	✓	✓	x	✓	x	x	x	x	✓	✓	✓	6/11
McKay et al., 2012	✓	✓	x	✓	x	x	x	✓	✓	✓	x	6/11
Lund et al., 2008	✓	✓	✓	✓	x	✓	x	✓	✓	✓	✓	9/11
Hughes et al., 2004	✓	✓	✓	✓	x	x	x	✓	✓	✓	✓	8/11
Mikesky et al., 2006	✓	✓	x	✓	x	x	✓	x	✓	✓	✓	7/11
Hussein et al., 2015	✓	✓	✓	✓	x	x	✓	x	✓	✓	✓	8/11
Foroughi et al., 2010	✓	✓	✓	✓	✓	✓	✓	x	✓	✓	✓	9/11
Rooks et al., 2006	✓	✓	x	✓	x	x	x	x	✓	✓	✓	6/11
van Leeuwen et al., 2014	✓	✓	✓	✓	x	x	✓	x	✓	✓	✓	8/11
Lim et al., 2008	✓	✓	✓	✓	x	x	✓	x	✓	✓	✓	8/11
Chaipinyo et al., 2009	✓	✓	✓	✓	x	x	✓	x	✓	✓	✓	8/11
Bennell et al., 2014	✓	✓	✓	✓	✓	✓	✓	x	✓	✓	✓	9/11
Score	19/20	20/20	11/20	20/20	5/20	5/20	7/20	4/20	20/20	20/20	14/20	6.55

✓-Yes; x-No

2.4 Statistical Analyses

In this meta-analysis post intervention means and standard deviations were gathered for groups having Conventional Physiotherapy intervention. Calculations of Standardised effect sizes at 95% Confidence intervals were carried

out. The results of different studies were compared with standardised effect sizes. According to Cohen¹⁰, effect sizes were categorized as weak ($d \leq 0.2$), small ($d=0.2-0.5$) moderate ($d=0.5-0.8$) and strong ($d \geq 0.8$).

2.5 Results and Discussion

In this review, twenty studies consisting of 1536 knee OA participants were included. The included studies had a good score in methodological quality with an average of 6.55, with the highest score of 11¹¹ and the lowest was 5^{1,12-13}. Although an average score of 6.55, indicates higher quality of the articles included, about 40% of the articles fell below the average level. Thus, this outcome raises a question pertaining to the quality of the systematic reviews as well as the RCTs we could include in this review. For this analysis, based on the guidelines of National Health and Medical Research Council¹⁴, the reported studies could be categorized and identified as having insufficient or satisfactory level or strong evidence. This procedure has been detailed categorically in one of our previously carried out systematic review study¹⁵.

3. DISCUSSION BASED ON PEDro SCORES ANALYSIS, DEMOGRAPHIC AND FOREST PLOT ANALYSIS

Following the NH & MRC¹⁴ criteria of demarcation; best evidence synthesis technique¹⁶ and PEDro Scale¹⁷ evaluations, out of 20 studies which were included in this metanalytic review, 3^{1,12-13} were observed to have grade - III-2 level of evidence; while 5 others^{6-7,18-20} were evident to fall under grade - III-1 level of evidence. Out of the remaining 12 studies, 8 studies^{8-9,21-26}, however were identified as having Grade II category of strong evidence.¹⁴ Finally, remaining 4 studies^{5,11,27-28} however were identified as having Grade I category of strong evidence¹⁴.

Apart from that, three studies^{1,12-13} were evident to receive PEDro Scale quality score 5 out of 11 and five other studies^{6-7,18-20} received PEDro Scale quality score 6 out of 11. Hence, as far as Hillier²⁹ recommended, these studies are supposed to be considered as above average quality studies, having high strength of evidence.¹⁶ Apart from that, studies conducted by Hughes and coresearchers²¹; Lim and colleagues²³; Chaipinyo and colleagues²⁴; van Leeuwen and coresearchers⁸ and Hussein and colleagues²⁶, were observed to achieve PEDro scores 8, while the studies of Mikesky and

coresearchers²²; Kumar and colleagues²⁵ and Gul and coresearchers⁹ received a score of 7 out of 11. Thus, these studies revealed moderately high level of authentic quality of evidence (refer to Table 2). Further to that, studies of Lund and coresearchers²⁸; Foroughi and colleagues²⁷; Knoop and coresearchers¹¹ and Bennell and colleagues⁵ received scores of 9, 10, 11 and 9 out of 11, respectively. Thus, these studies revealed very high level of authentic quality of evidence (refer to Table 2). To sum up, it may be postulated that the outcomes of this study indicated beneficial impact of the conventional physiotherapy training regimes in reducing pain among elderly and middle-aged both female and male individuals diagnosed with OA of knee.

4. DISCUSSION BASED ON CONTENTS OF DEMOGRAPHIC AND INTERVENTION CHARACTERISTICS

All the included studies had different protocol for Conventional Physiotherapy (see appendix). Bennel et al.⁵ for example, investigated quadriceps strengthening training without weight (10 times for 3 sets), bending of the knee (2 repetitions), step-ups (10 times for 3 sets), wall squats (10 times for 3 sets) and strengthening of hip muscle (5 times for 2 sets). The investigators observed significant improvement in physical function and substantial reduction in pain in knee OA participants, which were evident both among CP and control group participants as well. In another study carried out by Shyam et al.¹, the experimental group received isometric training consisting of isometric hip adduction training, straight leg raising (SLR) and quadriceps isometric exercise. All the exercise trainings were imparted following a protocol of 10 repetitions. In the first week, participants carried out 1 set of exercises for 2 times per day and gradually the exercise intensity got increased to 2 sets for 2 times a day until the end of third week. Finally, participants were instructed to perform 3 sets of exercises for 3 times a day, until the end of the intervention. At the end of the study, strengthening exercise regimes were found to reduce the level of perceived pain and the extent of disability and also an enhancement in muscular peak torque was noticed among knee OA participants.

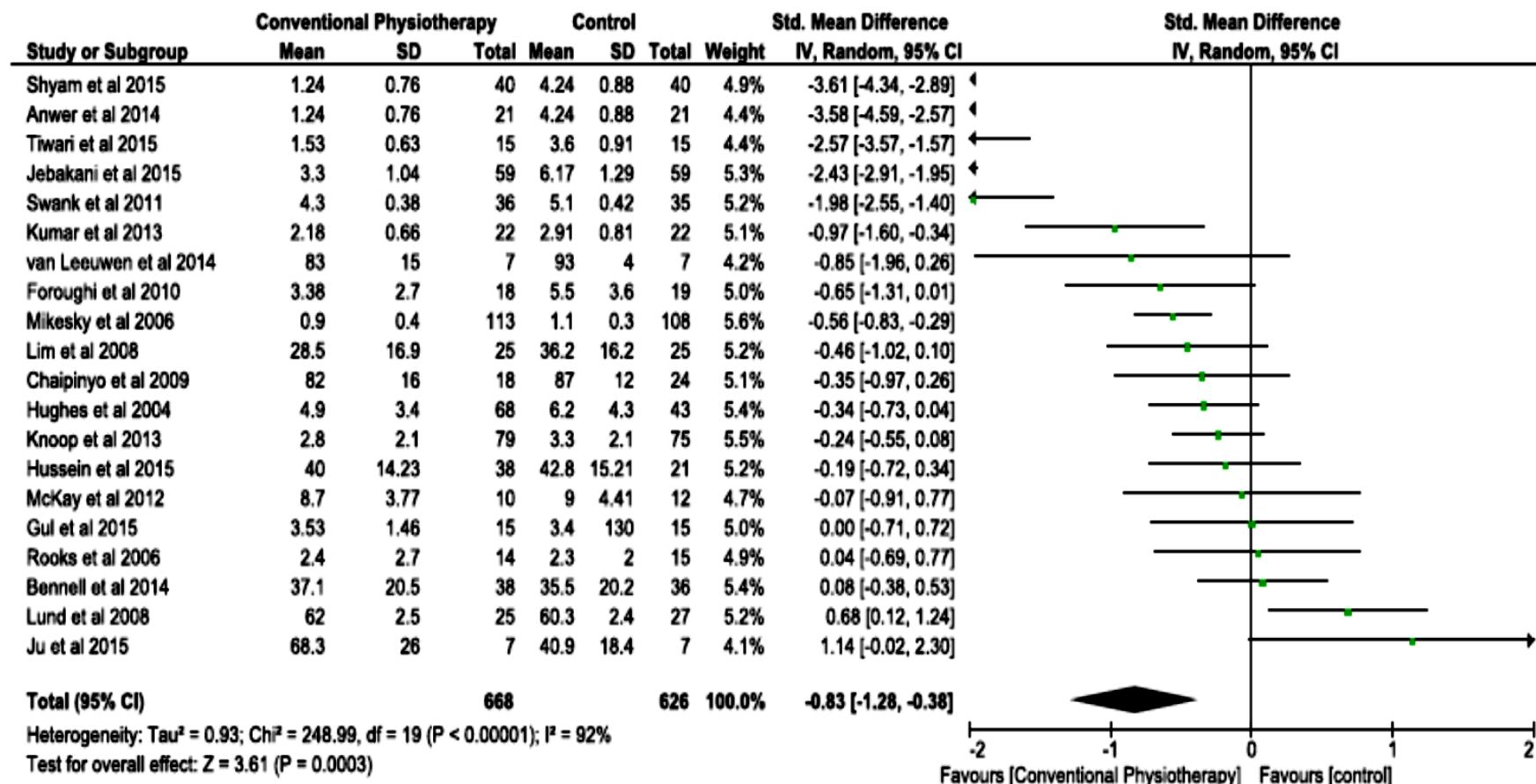


Figure 2

Forest Plot Depicting Effects of Conventional Physiotherapy in Reduction of Pain

McKay and his colleagues⁷ followed a protocol for the experimental group of participants, which started with warm-up aerobic activities for 10 minutes either by using stepper, treadmill, rowing ergometer or bicycle ergometer. Thereafter the participants of the experimental group were engaged in bilaterally designed exercises for lower body, which included - seated leg press, knee extension exercise, leg curl and standing calf raise activities following a protocol of 8 repetitions/set, for 2 sets. Their counterparts in the control group, alike those in the experimental group, followed warm-up activities for 10 minutes, which was followed by exercises for bilateral upper body exercises (viz., elbow extension and flexion exercises, chest press and latissimus dorsi exercises in sitting position for 8 repetitions/set, for 2 sets. Finally, at the end of the study in the experimental groups, beneficial impacts of exercise on improvement in strength of quadriceps muscles, enhanced mental health and increased speed of walking were noticed.

In this review the overall effect size for impacts of CP training in reducing pain among OA of knee patients was evident as -0.83 with a confidence interval of -1.28, -0.38. The heterogeneity of the included studies was evident as 92%, which is considered to be higher in the arena of clinical trials. Reason behind this extremely high percentage of heterogeneity lied in the differences evident in the methodology followed in the experimental studies included in this study, which were already detailed in the earlier section. The Chi² value was observed as 248.99 (P=0.001), with degrees of freedom of 19. In the meta-analysis, it can be noted that most of the studies favoured Conventional Physiotherapy in reducing the level of pain for knee OA participants. Out of twenty studies, only the studies carried out by Lund et al.²⁸ and Ju et al.¹² favoured other interventions or no-intervention condition to reduce the level of pain, while the studies of Bennell et al.⁵ and Rooks et al.¹⁸

marginally favoured other intervention conditions, and the study of Gul et al.⁹ neither favoured CP nor the control condition.

In summing up it may be said that impact of Conventional Physiotherapy for treating knee OA participants is favourable in reducing their level of perceived pain. It is worthy to be mentioned here that, we could include limited number of researches investigating the impacts of Conventional Physiotherapy in reducing pain among knee OA patients. Therefore, the results for the Conventional Physiotherapy might get altered if other related studies are included for meta-analysis in future.

5. LIMITATIONS OF THIS REVIEW AND INCLUDED STUDIES

This review study although highlighted some relevant aspects of contribution of conventional exercise training regimes, despite our best efforts, this study suffers from a few limitations. First of all, only twenty studies could be included for the systematic meta-analysis. Further to that, majority of the studies were not having very high-quality evidences. Few of the studies did not provide the mean differences, and thus we couldn't include those studies in meta-analysis, as without the mean-difference indices, meta-analytic Forest-plot evaluation would not be performed. Apart from that, the Forest-plot itself depicted that, three studies favoured control conditions, while two other studies slightly favoured no-treatment control condition as well. Thus, the efficacy of the conventional exercise interventions in reducing pain among elderly and middle-aged individuals suffering from OA of knee, was confirmed based on the articles revealing outcomes of moderately high-quality evidence in eight articles, and very high-quality evidences in four others.

6. CONCLUSIONS

A few authentic experimental studies revealed strong evidence of beneficial impacts of conventional physiotherapy exercise training, on reduction of perceived pain among elderly and middle-aged individuals diagnosed as suffering from OA of knee. Based on the outcomes of this review, it could be clarified that, majority of the studies included favoured conventional physiotherapy training as effective exercise regimes. This study from within its limitations emphasized that, the exercise trainings if imparted following rigorous methodology, those may lead to functional improvements, and consequent reduction of pain associated with OA of knee, among Malaysian elderly individuals. We hope that the findings of this study will be useful to specialist clinicians and exercise therapists working with elderly and middle-aged individuals, especially female individuals suffering from OA. This study will encourage future researchers to carry out more systematic reviews, after taking into consideration of plenty of authentic experimental evidences to enrich this field of study.

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8. CONTRIBUTION OF AUTHORS

Conceived and designed the experiments: SrS, SoS, AaS, NbR
 Collected data and performed the experiments: CmL, NbR, SoS
 Contributed with materials/analysis tools: SrS, SoS, AaS, NbR

Analyzed the data: SrS, SoS, NbR
 Wrote the paper: SoS, SrS, NbR
 Checked and edited the format of the paper: SrS, SoS, AaS, NbR, HaH
 Final approval: SrS, SoS, AaS, NbR, HaH

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APPENDIX

1. Demographic Characteristics of the Trial

Researcher	Diagnosis	Age	Population	Male/female	Outcomes
Shyam et al., 2015	Knee Osteoarthritis	65-85	80	NA	Pain, Isometric quadriceps strength, Knee function.
Anwer et al., 2014	Knee Osteoarthritis	40-65	42	13/29	Pain, Isometric quadriceps strength, Knee function.
Ju et al., 2015	Knee Osteoarthritis	65.7 ± 3.5	14	0/14	Knee joint muscle function, pain (VAS).
Swank et al., 2011	Knee Osteoarthritis	63	71	25/46	Pain, Strength, Function.
Kumar et al., 2013	Knee Osteoarthritis	40-65	44	19/25	Pain (NRS), Functional disability (WOMAC), Joint position sense (JPS) error.
Gul et al., 2015	Knee Osteoarthritis	56 ± 9.3	30	NA	Pain, Functional level.
Jebakani et al., 2015	Knee Osteoarthritis	50 – 65	118	47/71	KOOS pain, Symptoms, Activity of daily living, Quality of life.
Knoop et al., 2013	Knee Osteoarthritis	40 -75	159	62/97	Physical function, Knee pain severity GUG-test, Daily activities Performance, Upper leg strength, Proprioceptive accuracy, WQ35 (walking), CStQ15 (stair climbing), QR & S39 (rising and sitting down).
Tiwari, 2015	Knee Osteoarthritis	40-60	30	NA	Pain, Walking speed, Step.
McKay et al., 2012	Knee Osteoarthritis	63.5 ± 4.93	22	NA	Isometric quadriceps strength. Mobility, Pain, Self-reported function, Health-related quality of life, Arthritis self-efficacy.
Lund et al., 2008	Knee Osteoarthritis	68	79	17/62	Pain, (KOOS), Balance, Strength.
Hughes et al., 2004	Knee Osteoarthritis	74	150	NA	Endurance and strength of muscle, Pain, stiffness, physical function, Self-Efficacy (Arthritis Self-Management), Exercise Adherence Self-Efficacy, Adherence.
Mikesky et al., 2006	Knee Osteoarthritis	69	221	93/128	Pain, Functional limitation, Strength, General health status and depression scores.
Hussein et al., 2015	Knee Osteoarthritis	33-72	59	22/37	Knee effusion, Pain, Lequesne score, One repetition maximum for quadriceps, Quadriceps and hamstring reflex (EMG), Knee joint proprioception inaccuracy.
Foroughi et al., 2010	Knee Osteoarthritis	64± 8	54	0/54	Dynamic shank, Knee adduction angles, Knee adduction moment, strength of muscle, Gait speed, Pain, Stiffness, Disability.
Rooks et al., 2006	Hip and Knee Osteoarthritis	60 -67	108	48/60	Functional status, Pain, Strength of muscle.
van	Knee	Above	22	12/10	Feasibility, Strength, Functional tasks,

Leeuwen et al., 2014	Osteoarthritis	55			Relationships between quadriceps strength and physical performance.
Lim et al., 2008	Knee Osteoarthritis	67.2 ± 6.7	107	48/59	Knee adduction moment, Pain and physical Function (WOMACS), Step test score, Stair climb test score, Maximum quadriceps isometric strength.
Chaipinyo et al., 2009	Knee Osteoarthritis	Above 50	48	11/37	Pain, Function in daily living, Function in sport and recreation, Knee-related quality of life, Strength, Mobility.
Bennell et al., 2014	Knee Osteoarthritis	62.1 ± 6.9	78	36/42	Pain (VAS), Self-reported physical function (WOMAC).

NA- Not Available

2. Characteristics of Intervention of the Included Trial

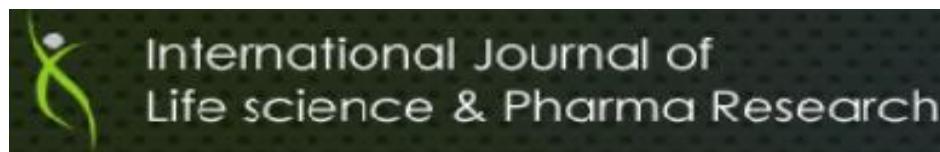
Researcher	Device	Contraction	Velocity	Repetitions
Shyam et al., 2015	NA	Isometric quadriceps exercise and Straight leg raising (SLR) exercise	-	10 repetitions for all the exercises. In the first week participants carried out 1 set of exercises for 2 times per day and gradually the intensity of exercise protocol increased to 2 sets 2 times a day till the third week.
Anwer et al., 2014	Ultrasound therapy, Plinth, Towel, Small pillow	Isometric quadriceps exercise (held for 5 seconds), Straight leg raising (SLR) with leg 10 cm lift and held for 10 seconds, Isometric hip adduction exercise (held for 5 seconds)	-	10 repetitions for all the exercises. In the first week participants carried out 1 set of exercises for 2 times per day and gradually the intensity of exercise protocol increased to 3 sets 2 times a day till the fifth week.
Ju et al., 2015	Jumper, Aero-step, IseMed 2000	Proprioceptive circuit exercise-half squat, straight lunge, side lunge, and one-legged balance exercise	-	10 times for 3 sets
Swank et al., 2011	Thera-Band bands	Resistance training using bands, Flexibility, and Step training start with warm up Squat, leg extension, leg curl, hip adduction, hip abduction, hip flexion, hip extension, foot plantarflexion, foot dorsiflexion, Step ups forwards/lateral both side, cool down.	-	All the exercises performed with low resistance, 10 times for 1 set at week 1 and 2 then progress to 2 sets at week 3 and 4. The same protocol were performed at week 5 until week 8 with moderate resistance.
Kumar et al., 2013	Ultrasound Therapy, Static Bicycle, Quads Table, Plinth, Weight Cuff, Weighted Pulley	Application of Ultrasound therapy with frequency of 1 MHz, intensity of 2.5W/cm ² . Warm up either with walking or static bicycling for 5 minutes and active stretching of the knee, hip and ankle for 2 minutes. Resistant exercise with gradually 10% increase in weight for every week. Proprioceptive exercise	-	10 times for 3 sets with 30 seconds gap between reps and 60 seconds gap between sets.

Gul et al., 2015	Hot pack	Hot pack was applied for 20 minutes. Quadriceps and hamstrings muscle flexibility, strengthening and co-contraction.	--	3 sessions/week for 4 weeks.
Jebakani et al., 2015	Hot pack	Hot pack was applied to the knee. Exercise regimes that consists of warm-up, active range of motion exercises for the knee, muscle strengthening exercises for the hip and knee, stretching exercise for the lower limbs and cool down.	--	3 sessions/week for 4 weeks.
Knoop et al., 2013	Treadmill	Week 1-4, specific knee joint stabilization exercise. Week 5-8), muscle strengthening training with gradually increase in knee resistant very week. Week 9-12, functional, participant-tailored exercises and aerobic exercise	--	Specific knee joint stabilization training- 15 times for 3 sets. Muscle strengthening exercises- 15 times for 3 sets in week 5 and 6. Week 7 and 8 for 20 times. Functional, participant-tailored exercises and aerobic training -10 times for 3 sets.
Tiwari, 2015	Weight cuff, pillows, plinth	Group A -four exercises (two for hamstrings and two for quadriceps), Group B participants performed two exercises for quadriceps strengthening. All the exercises were carried out with 1kg for the first 3 weeks and progress to 1.5kg for the next 2 weeks	--	25 to 30 times for 1 set and participants were allowed to take rest.
McKay et al., 2012	Treadmill, cycling ergometer, rowing ergometer, or recumbent stepper.	Warm-up session for 10 minutes either by using stepper, treadmill, rowing ergometer or bicycle ergometer for the experimental group. After that the participants of the experimental group performed exercises for bilateral lower body which included, seated leg press, knee extension exercise, leg curl and standing calf raise. The control group of this study carried out warm-up session for 10 minutes same as the experimental group, followed by exercises for bilateral upper body which included elbow extension and flexion exercise, chest press exercise and latissimus dorsi exercise in sitting position.	--	Bilateral lower body exercises and bilateral upper body exercises – with 8 repetitions for 2 sets.
Lund et al., 2008	Rubber band, or weight resistance (leg press), aqua noodles, rings, kick boards, pool	Warm-Up, Strengthening/Endurance Exercise, Balance Exercise and Stretching Exercise, Cool Down.	--	2 sessions/week for 8 weeks.
Hughes et al.,	Cuff weights,	Resistance training and fitness	--	3 sessions/week for 8 weeks.

2004	therabands, chair, bicycle ergometer	walking-60 minutes, Discussion-educational component-30 minutes. Warm-up and cool-down periods that consists of neck, trunk, and extremity range of motion exercises. Static and dynamic sitting and standing balance exercises. Fitness walking progresses from 40% to 60% of maximum heart rate.		
Mikesky et al., 2006	Cybex, elastic bands	Warm-up and cool-down session, resistance exercises consists of seated rows, wall squats, standing leg curls, leg presses, seated chest presses, leg curls, wall pushups and seated back rows. Flexibility exercises involved the whole body	--	Resistance training – 8 to 10 times for 3 sets and progress to 2 times for 2 sets. Participants need to perform 10 times every exercise in flexibility training.
Hussein et al., 2015	Cybex weight machine, Interferential, ice packs, balance board	Flexibility and Isotonic (dynamic) resistive exercise programs, Physiotherapy (interferential current 10 minutes and ice packs for 15 minutes), Analgesic medications, Balance exercise	--	Participants need to perform isotonic (Dynamic) resistive exercise for 8 repetitions at the intensity of 40 percent of 1RM.
Foroughi et al., 2010	Keiser machine	Exercise intervention- unilateral knee extension, standing hip abduction and adduction; and bilateral knee flexion, leg press, and plantar-flexion (exercises at 80% of participant's peak muscle strength, increase 3% of resistance per session. Isometric exercises.	--	Study group - 8 times for 3 sets. The participants were allowed to take pause for 10 to 15 seconds between repetitions and also 1 to 2 minutes' gap between sets. Control group – 8 times for 2 sets.
Rooks et al., 2006	Pool, stationary bicycle elliptical device, resistance machines,	Single-joint movements. Weeks 4–6, exercise sessions consists of a total body fitness program such as flexibility, strength and cardiovascular, exercises.	--	First 3 weeks, participants performed 8 to 12 times for 1 to 2 sets of single-joint movements. Strength training- 8 to 12 times for 2 sets. Hold for 20 seconds and repeat 2 times in flexibility exercises.
van Leeuwen et al., 2014	Dumbbells or plates	Therapy consists of aerobic exercise, resistance exercise, training of walking with aids, activities of daily life training, information and advice, and maintenance of mobility.	--	Resistance training- 15 times for 3 sets Squat exercise and home program – 2 to 3 sessions/week.
Lim et al., 2008	Ankle weight sand, Thera-Band	Quadriceps strengthening exercises (Isometric knee extension at 60 degrees' knee flexion, Inner range knee extension, Straight leg raise, Long arc knee extension and Isometric knee extension at 30 degrees' knee flexion).	--	First 2 weeks' participants need to perform 10 times for 2 sets and progress to 3 sets until the week 12.
Chaipinyo et al., 2009	--	Balance group- stepping forward and backward than sideways for	--	30 times for stepping forward and backward than sideways

		each leg and bilateral mini squat (15-30 degrees of knee flexion). Strength group- isometric knee extension in sitting for each leg hold for 5 seconds, 5 days per week.		for each leg, bilateral mini squat and isometric knee extension.
Bennell et al., 2014	Ankle weights, elastic bands	Home exercise program- weight-bearing neuromuscular exercises focused on quality and control of movement (6 exercises). 4 sessions/week for 24 weeks.	--	Weight-bearing neuromuscular exercises focused on quality and control of movement (6 exercises, consists of knee bending, wall squats, step-ups - 10 times for 3 sets. Hip muscle strengthening 5 times for 2 sets. Balance for 2 minutes. Non-weight-bearing quadriceps strengthening exercises – 10 times for 3 sets.

NA- Not Available



EXERCISE INTERVENTIONS TO REDUCE THE LEVEL OF HBA1C FOR EFFICIENT AND EFFECTIVE MANAGEMENT OF TYPE 2 DIABETES MELLITUS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

This review study determined the effects of exercise interventions to reduce the level of HbA1c for efficient and effective management of Type 2 Diabetes Mellitus (T2DM). Electronic databases including PubMed, EMBASE and Science Direct were searched for the published literature. Overall effect size with 95% confidence intervals (CIs) was used to assess the strength of the relationship between interventions and T2DM by using a random effects model. Heterogeneity was also evaluated. 10 randomized controlled experimental studies were selected and included in the review. Studies having drug co-interventions were excluded. Overall estimate of the mean differences of the exercise interventions showed that the total effect size for reduction in HbA1c to manage T2DM was about -0.74 with a 95% confidence interval (CI) of -0.98 to -0.50 and the I^2 value is 62%. Exercise interventions are moderately effective in reducing HbA1c to manage type 2 DM efficiently.

KEYWORDS: *Type 2 Diabetes Mellitus; HbA1c; Exercise Training; Meta-Analysis*

1. INTRODUCTION

Individuals diagnosed as suffering from insulin-resistant diabetes are unable to control their blood sugar levels, since cellular activities in response to insulin gets grossly impaired. Generally, there are three types of diabetes mellitus, type 1 (where body doesn't produce insulin), gestational diabetes (when insulin is less effective during pregnancy) and the other one is type 2 diabetes

where insulin is being produced but bodies are not responding, that is, bodies are insulin resistance.¹

In 2015, 415 million individuals diagnosed with diabetes and this was projected to increase up to 642 million by the end of 2040¹. Among those individuals, 90% was diagnosed as having type 2 diabetes mellitus or T2DM.¹ Since T2DM is a chronic disease, it may lead to a series of severe complications and comorbidities like blindness, amputation, kidney disease, heart disease etc. Thus,

T2DM individuals require constant monitoring, medical care, patient self-care and education to prevent various complications and to reduce the risk of long-term diseases.² Hence, to control and manage T2DM efficiently constant monitoring of the blood sugar level or glycaemic status of the diabetic patients are very important. It has been recommended by the American Diabetes Association (ADA) that diabetic patients must need to monitor their blood glucose-levels by self-monitoring of blood glucose (SMBG) and also by health care providers.³ More significantly, measurement of glycosylated haemoglobin (HbA1c) is essential to have a more proper and accurate status of the blood glucose level of the patients, which basically quantify average glycaemia over several weeks and months, thereby complimenting everyday testing by the patients' themselves.³ Therefore, it is an imperative issue to have effective regulation over HbA1c and reducing the heightened levels of HbA1c to keep it within the range of blood glucose-levels recommended for T2DM patients.⁴

From the standpoint of diabetic care, it is always crucial to maintain HbA1c and also equally important to manage other risk factor including obesity, hypertension and dyslipidaemia. For these reasons, efficient application of interventions and effective management of this metabolic disorder is of vital importance. Physical activity and exercise interventions tailored for the T2DM patients have been recommended by the American Diabetes Association (ADA)³ and American College of Sports Medicine (ACSM)^{5,6} for quite a few decades. A confusion however, regarding the usage of the terms 'physical activity' and 'exercise' is observed, and people often tend to use these terms interchangeably. Basically, these two expressions denote two different concepts.⁷ Firstly, physical activity means any physical movement created by skeletal muscles which results in energy usage⁸ and it can be measured in kilocalories. Physical activities can be of different sorts like occupational, sports, conditioning, household, or other activities. Exercise on the other hand, represents physical activity which is deliberate, structured, and repetitive and has as a final or a midway objective to improve or maintain physical fitness.⁸ Here physical fitness means a set of traits, which are either health- or skill-related; and physical fitness

can be measured with different types of tests. Hence, it is not only necessary to understand the importance of physical activity, but also the role of exercises in the management of T2DM patients, needs to be paid adequate attention.

A considerable amount of experimental research literatures has been published in attempt of identifying effective, yet safer exercise intervention programs and also several meta-analytic and systematic reviews have demonstrated improvement in health outcomes with self-management support programs in T2DM management.⁹ However, a chunk of recent meta-analytic systematic reviews either focused only on the exercise interventions¹⁰⁻¹¹ or on physical activity programs as a whole¹⁰⁻¹² to tackle the burden of T2DM as a whole. These meta-analytic studies and few other studies were carried out considering optimal methodological care for search strategies; selection of studies; data extraction; synthesis and interpretation¹⁰⁻¹², while those were observed to have quite a few serious limitations. In one study¹¹ for instance impact of resistance training on T2DM was studied, in which circuit weight training (CWT) sessions were observed as varied from only 5 types of exercises up to even 11 types of exercises; and exercise intensity varied widely from 40–80% of 1 RM, and in some cases, intensity was not mentioned at all (which is considered as serious limitation). Frequency of exercise activities were also observed to vary from two to five times per week; while total duration of intervention sessions varied from less than one month to even 6 months of duration. Similar to that, exercise sets varied from 1 to 2 sets, while repetitions varied from only 8 repetitions up to 20 repetitions per set. Irregularity was also noticed in rest periods allowed between the sets, which has got huge significance in case of exercise related researches on metabolic syndrome and distress (varied from only 30 seconds rest between exercises up to 120 seconds of rest between the exercise sets).¹¹

In that same systematic review¹¹ (though it was not meta-analytic review) resistance training (RT) sessions were observed to vary from 5 to 7 exercises; RT intensity varied from 40–70% (wherein one study didn't even mention the training intensity) of 1 RM (one repetition maximum). Exercise training sets also varied similarly from 2 to

3 sets of 10 – 15 repetitions. In case of introduction of aerobic training (AT), types of AT varied in wide-range from walking; jogging and cycling to various different modes; and the AT intensity varied widely ranging from 40–85% HRR and even HR_{peak} . As it was observed in case of CWT, in RT sessions too, duration of training sessions also varied from 30–55 minutes, while one study did not mention the duration of exercise at all.¹¹

In another recent and acclaimed systematic review with meta-analysis¹², numerous studies were included, while no parity in exercise or community-based physical activity (PA) intervention were maintained. Included studies were observed to carry out interventions such as, structured resistant training program; pedometer-based walking program; regular yoga classes, which were grossly considered as PA sessions, while individual sessions with physical therapist focusing on leg strength; regular low-impact exercise routine led by nurses and even physical therapist- directed exercise counselling; Stage-targeted booklet addressing: Motivation Self-efficacy; Goal-setting; Social support; Problem-solving etc. were also included in community-based PA intervention programs.¹² Further to that, while attempting to carry out the risk of bias assessment, the authors confirmed that out of the 22 studies they analysed, only one study (only 4.5%) was identified as having low risk of bias, while 15 (68%) studies were classified as having moderate risk of bias, and the remaining six (27%) studies were rated as high risk of bias. Moreover, only three (13.6%) studies were reportedly having assessor blinding, and only four (18%) studies were evident as presented summary results, estimated effect sizes and precision estimates and 12 (54.5%) studies were observed to employ objective measure of physical activity interventions followed by their participants.¹² Based on the the guidelines of National Health and Medical Research Council¹³⁻¹⁵ criteria of demarcation, 50% of the reported studies were lacking in strength of evidence (based on PEDro Scale scores), and hence could be considered as low-quality experimental studies.

Facing these situations, we intended to concentrate on the studies carried out following systematic approaches in introducing exercise

intervention program. At par with the American Diabetes Association and American College of Sports Medicine Position stand⁵⁻⁶, which was clarified in the year 2000, we tried to concentrate on experimental studies, which were carried out following the directives prescribed by ADA and ACSM. This being the reason, we intended to search for the randomized control trials (RCTs), which investigated impacts of exercise intervention on T2DM following rigorous and meticulous methodological considerations. Taking into consideration of the methodological concern, we looked into the issues pertaining to maintenance of consistency in pre-exercise routines; frequency; intensity and duration of exercise activities and in every aspect of exercise habits.^{2,3,5,6} For instance, exercise schedules were kept on 3 non-consecutive days per week, considering 5-min warm-up and 5-min cool-down period of *Low-intensity* stationary cycling and~ 45min of *high-intensity resistance training* (dynamic exercise involving concentric and eccentric contractions).¹⁶

Hence, the objective of this review is to pull together all relevant existing evidence that evaluate exercise intervention to manage the burden of T2DM by reducing HbA1c level in type 2 diabetic patients.

2. METHODS

2.1 Search strategy

A search was conducted in the databases available in PubMed, Google Scholar, Scopus, Cochrane, EMBASE and Science Direct, using variations of the search string contained in Table 1. Reference lists of included studies were also searched for further applicable studies. We searched into the aforementioned databases for randomized controlled trials (RCTs) that compared standard or usual care with exercise interventions, facilitating desirable changes in lifestyle. The following terms were used in the search: diabetes, type 2 diabetes, HbA1c, impaired glucose tolerance, metabolic distress, lifestyle, health education, exercise intervention and physical activities.

Table 1
Search Strategy

Databases	Search Items
PubMed, Google Scholar, Scopus, Cochrane, EMBASE and Science Direct	<p>The following terms as words within the title, abstracts or texts of papers:</p> <p>(1) “health”, “diabetes”, “type 2 diabetes,” “impaired glucose tolerance,” and “metabolic distress”.</p> <p>(2) “lifestyle” or “health education” or “exercise intervention” or “physical activities” as words within the title, abstracts or texts of papers</p>

Since RCTs, which were carried out following the directives prescribed by ADA and ACSM, were only taken into consideration, in this review, articles from 2000 to 2015 were included. RCTs categorized and identified as having satisfactory level or strong evidence were only selected following NH & MRC¹³ criteria of demarcation; best evidence synthesis technique.¹⁴ Studies published in languages other than English were excluded. RCTs that included drug and nutritional co-interventions, were also excluded. Further to that, the studies which were not prospective randomized trials, did not enrol patients with type 2 diabetes, or did not investigate interventional programs relating to exercise were also excluded from analysis.

2.2 Study selection and Screening

The selection criteria set for this review followed five specified characteristics of studies. First, the searches of the studies were accomplished within 31st December, 2015, and were limited to RCTs of at least satisfactory level of evidence, published in English language. Secondly, targeted population of the RCTs were specified only for patients diagnosed with T2DM. Third, the studies had to evaluate any category of structured exercise (aerobic, resistance, or a combination of both) with a control group of patients with type 2 diabetes to manage T2DM. Finally, those studies evaluated at least one of the following outcomes: Glycated haemoglobin (HbA1c, A1C, or Hb1c; sometimes

also HbA1c or HGBA1C) and reported means and respective dispersion values of outcomes at post intervention of the intervention and control groups.

The screening process was carried out in four stages. Firstly, all articles were first screened on the basis of the titles and abstracts. Secondly, the screened and short listed articles were thoroughly read. Thereafter, the reference lists of the short listed articles were also screened. Lastly, in the fourth and last step, based on the aforementioned selection criteria for this review, final screening from the short listed articles was carried out.

2.3 Data Extraction

At first studies were screened for compatibility by one author (FS) based on the selection criteria by their key words, titles and abstracts. Two other authors (SS & SS) once again independently screened the titles and abstracts of articles. After that, all of the authors assessed the selected materials independently in a standardized manner. All the findings were compared and differences were resolved by consensus among three authors. After that full texts of the studies were reviewed at length, with disagreements resolved via discussion amongst the authors. A standard review form was used to extract data from those studies, which included the name of the first author; year of publication; number of participants; age and gender of the participants; comparators used; intervention regimes incorporated in the study/control group, and results.

2.4 Comparators Used

In determining the effects of exercise interventions for T2DM, the choice of comparators against which the interventions are assessed, play a vital role. In this regard, studies included could be categorized in two parts. In first part, the studies were included, which assessed the exercise intervention against “usual care or standard health care”. In these studies, impacts of exercise intervention were compared to situations where usual/standard care treatments were provided to the subjects by the general physicians or by themselves. In other cases, studies compared the impact of

exercise intervention to an alternative intervention scenario where participants would be forced to obtain the intervention through alternative procedure.

2.5 Methodological Quality Assessment

Methodological quality of all included studies was evaluated with the help of Physiotherapy Evidence Database (PEDro) scale.^{15,17} This scale consists of 11- point scale to evaluate the methodological issues of studies. PEDro has been used widely by researchers as a critical appraisal tool.^{15,17}

Table 2

Methodological assessment of exercise intervention studies with Physiotherapy Evidence Database (PEDro) scores

Study	1. Eligibility criteria?	2. Random allocation?	3. Concealed allocation?	4. Baseline Similarity?	5. Blind participants?	6. Blinding therapists?	7. Blinding assessors?	8. Follow?	9. Intention to treat analysis?	10. Group comparison?	11. Point and variability?	Score
Castaneda et al (2002)	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	8/11
Maiorana et al (2002)	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	7/11
Cuff (2003)	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	9/11
Tessier (2000)	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	6/11
Sigal (2007)	Yes	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	6/11
Dunstan (2002)	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	9/11
Bweir (2009)	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	7/11
Ibanez (2005)	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	7/11
Fritz (2006)	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8/11
Arora (2009)	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	9/11
Score	10/10	9/10	4/10	10/10	0/10	0/10	4/10	10/10	10/10	10/10	9/10	6.9

2.6 Risk of Bias Assessment

Risk of bias assessment was conducted using Physiotherapy Evidence Database (PEDro) scale^{15,17} (Table 2). This scale is used for quality assessment and as a tool for risk bias assessment as well. This scale consists of 11-point scale to evaluate the risk bias, which is better than the checklist suggested in other study by Plotnikof and co-researchers¹², since the checklist employed by van Sluijs and Young¹⁸⁻¹⁹, lack in strength of assessment of blinding. In assessment of risk of bias the following items were assessed: (1) Eligibility criteria reported separately for each group; (2) Randomized allocation was clearly described and adequately completed; (3) Concealed random allocation was done or not; (4) Baseline similarity was checked or not; (5) Blinding of participants; (6) Blinding of therapist; (7) Blinding of assessor; (8) Follow-up; (9) Intention-to-treat analysis; (10) Group comparison analysis; and finally (11) Point and variability was analysed or not. Each item was scored as “Yes”, or “No” indicative analyses, while every “Yes” was scored as 1 point and “Nos” were scored as 0. High risk of bias was identified, if the study obtains score in between 0–3. Moderate risk of bias studies was regarded as those with a score in between 4 – 7, and scores from and above 8 was considered as low risk of bias presented.^{15,17} The assessment however indicated that, for the assessment of exercise intervention studies, majority of the studies (more than 66% of studies) were identified as having low risk of bias, while less than 33% of the studies were observed to have moderate or low-moderate risk of bias.

2.7 Statistical Analyses

In this review, for Meta-analytical investigation we have used Review Manager 5.3

software (RevMan v;5.3), in which means and standard deviations of the post intervention state of selected studies were taken into consideration for the participants of the intervention and control/usual care groups. 95% confidence intervals and standardized effect sizes were calculated. The standardized effect sizes allowed us to compare the results among different studies. The data were separated based on the outcomes of HbA1c. Effect sizes were classified as weak ($d \leq 0.2$), small ($d = 0.2-0.5$) moderate ($d = 0.5-0.8$) and strong ($d \geq 0.8$).²⁰

3. RESULTS AND DISCUSSION

3.1 Literature Search

On the basis of the electronic database search strategy, 137 potentially relevant studies were identified by initial literature search and searches of reference lists. Thereafter nine of the studies were excluded for duplication. Among the remaining 128 studies, 31 studies met the criteria for data extraction requirements and had sufficient information to be included in this review and the rest of the studies were excluded from the review process. Then 31 records were thoroughly assessed based on the eligibility criteria and out of that, 10 studies were selected and included in the review. Under the exercise intervention programs, three forms of exercise were studied: aerobic exercise, resistance exercise and a combination of aerobic and resistance exercise. Some of the studies were evident to include more than one form of exercise exposure. A flow diagram of the process of selection is shown in Figure 1. Brief characteristics of studies on exercise interventions included in this review are illustrated in appendix.

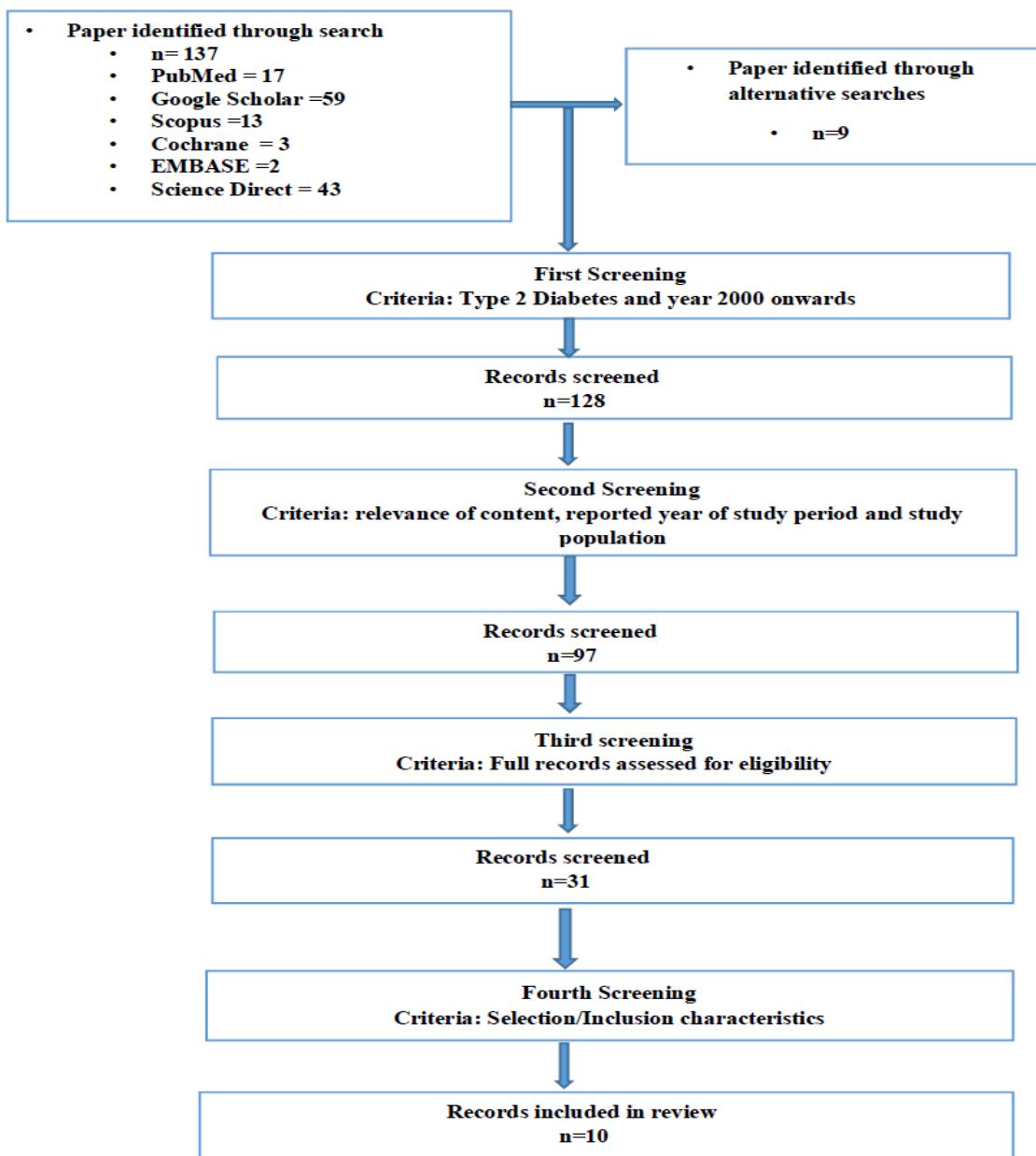


Figure 1
PRISMA Flowchart

3.2 Methodological Quality

Every article was assessed on the basis of 11-point PEDro scale.^{15,17} The average score of the exercise intervention studies which were selected for this review was 6.9. The highest score was 9 and the lowest was 7. This evaluation of methodological quality of the RCTs included in the study by using

3.3 Demographic Characteristics and Outcome Measures

The RCTs included in this study were evident as having heterogeneity in the number of

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the PEDro Scale analysis, was one of the unique feature of this study, which was not used by any other studies up to this level of accuracy. Among the selected studies most of the studies did not score on blinding participants, therapists and assessors (Table 2).

participants in the research. The maximum number of participants included among studies were 251 and the minimum participants were 9. There existed a lot of inconsistency in the ratio of sex of the

participants (male and female) included, since most of the studies recruited larger number of female participants. The primary outcome measure reported in all of the studies were HbA1c (see appendix). Excepting the studies done by Ibanez²¹ and Fritz²², majority of the RCTs reported to have beneficial impacts of exercise interventions, in reducing HbA1c and in improving the management of T2DM diabetes. The aforementioned studies however reported no post-intervention alteration in the level of HbA1c.

3.4 Pooled Analysis

In this study, the standardized mean difference analyses of the effect sizes for the outcome of HbA1c for the exercise intervention group showed a homogenous, negative effect that ranged from weak to strong. The details of the effect size and 95% CI for exercise interventions are shown in Table 3.

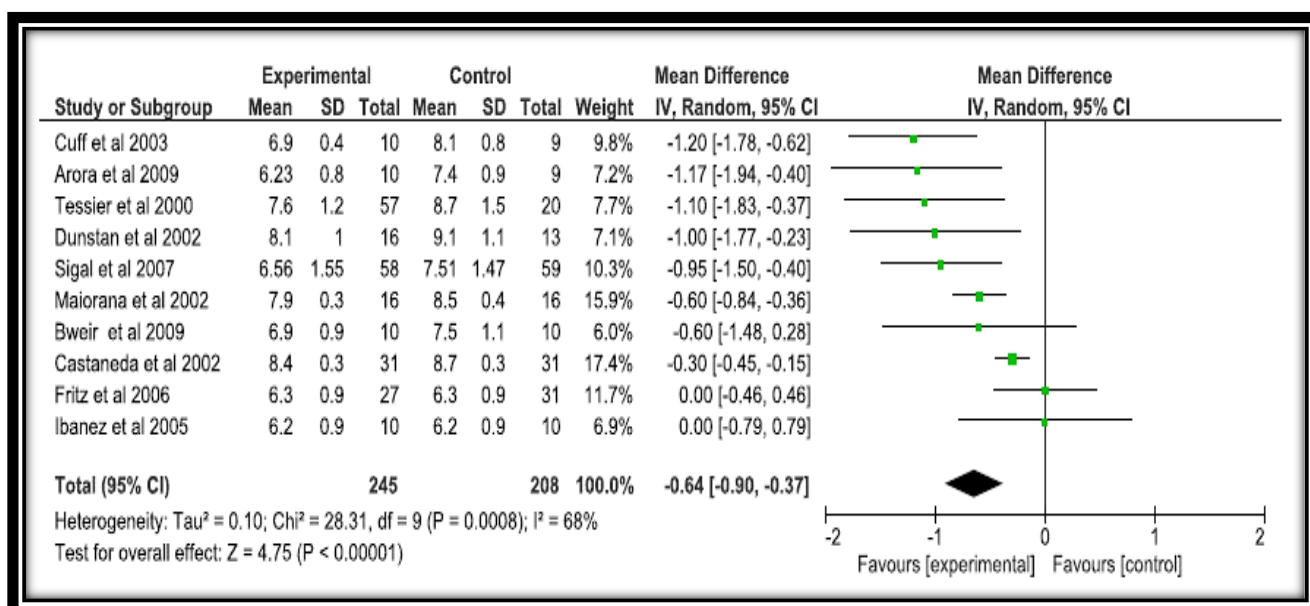
Table 3
Exercise interventions' effects on HbA1c outcomes

Researcher	Exercise Intervention	Usual care	Std. Mean Difference 95% CI		
			IV	Lower	Upper
Castaneda et al (2002)	8.4±0.3 (31)	8.7±0.3 (31)	-0.30	-0.45	-0.15
Maiorana et al (2002)	7.9±0.3 (16)	8.5±0.4 (16)	-0.60	-0.84	-0.36
Cuff et al (2003)	6.9±0.4 (10)	8.1±0.8 (9)	-1.20	-1.78	-0.62
Tessier et al (2000)	7.6±1.2 (57)	8.7±1.5 (20)	-1.10	-1.83	-0.37
Sigal et al (2007)	6.56±1.55 (58)	7.51±1.47 (59)	-0.95	-1.50	-0.40
Dunstan et al (2002)	8.1±1.0 (16)	9.1±1.1 (13)	-1.00	-1.77	-0.23
Bweir et al (2009)	6.9±0.9 (10)	7.5±1.1 (10)	-0.66	-1.48	0.28
Ibanez et al (2005)	6.2±0.9 (10)	6.2±0.9 (10)	-0.70	-1.49	0.09
Fritz et al (2006)	6.3±0.9 (27)	6.3±0.9 (31)	-0.60	-1.02	-0.18
Arora et al (2009)	6.23±0.8 (10)	7.41±0.9 (9)	-1.18	-1.95	-0.41

Pooled analysis of the mean differences showed that the overall effect size for improvement in HbA1c due to exercise interventions was about -0.64 with a 95% confidence interval (CI) of -0.90; -0.37 (Figure 2). The I^2 value of 68% suggests substantial heterogeneity of the studies. Out of 10 studies analyzed 8 studies; such as Castaneda et

al²³, Maiorana et al²⁴, Cuff et al²⁵, Tessier et al²⁶, Sigal et al²⁷, Dunstan et al¹⁶, Arora et al²⁸ and Bweir et al²⁹ favoured experimental group i.e. exercise intervention as being effective in reducing HbA1c for the efficient management of T2DM compared to control group i.e. usual care.

Figure 2
Standardized mean difference analysis for exercise interventions' studies



Based on the studies that implemented exercise interventions incorporating aerobic exercise along with resistance training it could be revealed that the intervention techniques employed to manage T2DM in populations were well enough effective in facilitating glycaemic control. Regularized and systematically monitored physical exercise is a feasible and acceptable modality of treatment in the population with T2DM, in reducing the HbA1c levels of these individuals.

3.5 Discussion

Exercise interventions were generally found to reduce HbA1c even though more recently the beneficial impacts of exercise on other parameters were also investigated²⁵. It has been observed that either aerobic or resistance training alone improves glycaemic control in type 2 diabetes, but the improvements are greatest, when in combination with aerobic and resistance training a systematically tailored exercise program is prepared.²⁶ The most interesting question however to be addressed, is not the effect of aerobic/resistance exercise itself, but the effects of exercise intensity, especially impacts of vigorous exercise versus moderate physical activity (typical walking). Aerobic exercise intervention being the most common form or preferred exercise intervention, it has always been researched extensively for the management of type

2 diabetes mellitus. In advent of sophisticated and easily available and viable metabolic monitoring systems, meticulously designed and programmed resistance exercise intervention has been recognized as a useful therapeutic training procedure for the treatment of a number of chronic diseases. These may include reduction of multiple cardiovascular risk factors and the improvement of insulin action on tissue as well, leading favourably on prevention and treatment of type 2 diabetes.²⁷ Whether compared to aerobic training or resistance training alone, combined introduction of resistance and aerobic training offers better beneficial impacts on glycaemic control in individuals with T2DM is an issue that has been adequately addressed by a number of studies^{25,28-29}.

Furthermore, specific proportion of combination of aerobic and resistance training, in terms of frequency; intensity and duration —as opposed to separate introduction of either aerobic or resistance training—is another interesting research question, that has been addressed in the study by Cuff et al.²⁸ The primary outcome was a change in HbA1c from baseline to termination of the intervention. The absolute change in HbA1c was evident as significantly higher in both the aerobic and the resistance training group compared with the control group. When compared either with aerobic training alone or with resistance training alone,

combined exercise training resulted in an additional change in HbA1c that achieved statistical significance. According to Castaneda et al²³, supervised progressive resistance training (PRT) resulted in reduced plasma glycosylated haemoglobin levels (from 8.7 ± 0.3 to $7.6 \pm 0.2\%$), increased muscle glycogen stores (from 60.3 ± 3.9 to 79.1 ± 5.0 mmol glucose/kg muscle), and reduced the dose of prescribed diabetes medication in 72% of exercisers. PRT subjects versus control subjects also increased lean mass reduced systolic blood pressure and decreased trunk fat mass. In addition to that, Maiorana et al²⁴ has demonstrated that a circuit training (CT) program, combining aerobic and resistance exercise has increased muscular strength with training whilst skinfolds, body fat and waist: hip ratio significantly decreased, while simultaneously HbA1c and fasting blood glucose levels got decreased. This phenomenon of introduction of high-intensity progressive resistance training, has been observed by Dunstan et al¹⁶, even in the older diabetic patients, who observed effective improvement in glycaemic control, and also moderate extent of reduction in weight. Therefore, from the studied literature it can be said that the benefits of aerobic exercise and resistance exercise are well documented and the effects of those interventions in patients with T2DM are widely perceived to be beneficial and in general, the results indicated that a combined training program of strength and aerobic could induce even more beneficial effects for the patients suffering from type 2 diabetes mellitus.

From the viewpoint of statistical analyses, overall estimate of the mean differences of the exercise interventions showed that the total effect size for improvement in HbA1c in regulation of type 2 DM was about -0.64 with a 95% confidence interval (CI) of -0.90 to -0.37. The I^2 value of 68% suggest substantial heterogeneity of the studies. The estimate of between study variance Tau^2 was about 0.10. Observed I^2 value revealed higher than moderate extent of heterogeneity³⁰, but as Higgins and his colleagues³⁰ pointed out, in meta-analytic reviews on clinical population, especially if numerous studies are performed by different groups of researchers in different places on different population and also with different methods, and all end up estimating the same underlying parameter,

high level of heterogeneity cannot be avoided.^{30,31} From the perspective that in a meta-analysis heterogeneity is inevitable, as far as Higgins himself opines, he confirms that any extent of heterogeneity is acceptable, provided that the data are correct and that the predefined eligibility criteria for the meta-analysis are sound.^{30,31} As we perceive it, the observed variation in the study outcomes probably occurred mostly due to the differential sample size³¹, which could be minimized if RCTs having wide-ranges of variability in sample size could be excluded. The other option could be if instead of random-effects model, analyses could be repeated with fixed-effects model¹⁰, which we acknowledge as one of the limitations of this study. The effects of exercise intervention as it was revealed through meta-analysis however, could be considered as strong enough to confirm facilitative impacts of exercise in regulation of T2DM effectively.

Based on wide 95% CI and the wide range of effect sizes, however a definitive evidence that exercise interventions are effective enough in reducing the level of HbA1c for effective and efficient management of T2DM however cannot be concluded. Additionally, it should also be noted that interpretations of the findings related to interventions to manage T2DM are confined to the few studies included in this review. Moreover, several interventional studies related to exercise for managing T2DM were excluded only because the studies did not report means and respective dispersion values of outcomes at post intervention of the intervention and control groups. Methodological biases such as lack of concealment, blinding of subjects and therapist were evident in most of the trials. In addition to that, the studies were of varied scopes and those were observed to include differential regimes of intervention. In consequence, comparison between the outcomes of the studies became utterly difficult.

Nevertheless, these limitations had definitely prompted the need for future studies to confirm these findings and to augment the research fundamental basis to determine the best possible intervention regime in managing HbA1c levels for treating T2DM more effectively and efficiently. Thus from this analysis it can be noted that exercise interventions do contribute towards effective management of T2DM by reducing HbA1c levels.

But it should also be noted that, these findings may get altered or modified with inclusion of numerous

related studies to the meta-analysis.

4. CONCLUSIONS

Exercise interventions (aerobic exercise, resistance exercise and combined exercise training are reasonably effective in regulating and reducing the glycated haemoglobin (HbA1c) level of the type 2 diabetic people. These interventions are also operational to enhance the sense of physical well-being in this population. Further researches with rigorous methodological concerns are required to determine the long-term efficacy of multi-component interventions on reducing HbA1c for efficient management of T2DM and the specific contributions of each of the components of intervention regimes onto the outcomes are required to delineated.

5. ACKNOWLEDGEMENTS

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6. CONTRIBUTION OF AUTHORS

Conceived and designed the experiments:

FaS, SoS, NBR

Collected data and performed the experiments:

FaS, SrS, SoS, NBR, WMIWM

Contributed with materials/analysis tools:

FaS, SrS, SoS, NBR

Analysed the data: FaS, SrS, SoS

Wrote the paper: FaS, SrS, SoS

Checked and edited the format of the paper:

FaS, SrS, SoS, NBR

Final approval: FaS, SrS, SoS, NBR, WMIWM, MSHI

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APPENDIX*Characteristics of studies on exercise interventions included in review*

Author	Population	Comparators Used	Intervention	Duration	Results												
Castaneda et al (2002)²³	62 Latino older adults (40 women and 22 men; mean \pm SE age 66 ± 8 years)	Usual care/standard care	16 weeks supervised progressive resistance training (PRT)	45 min session -5 min warm up -35 min PRT using five pneumatic resistance training machines (chest and leg press, upper back, knee extension, and flexion); -5-min cool-down. -3 sets of 8 repetitions on each machine per session.	<table border="1"> <tr> <td colspan="4">Post Intervention</td> </tr> <tr> <th>Outcome measure</th><th>Control group (usual care)</th><th>Intervention group (PRT)</th><th>Results</th></tr> <tr> <td>HbA1c</td><td>$8.3 \pm 0.5\%$</td><td>$7.6 \pm 0.2\%$</td><td>↓</td></tr> </table>	Post Intervention				Outcome measure	Control group (usual care)	Intervention group (PRT)	Results	HbA1c	$8.3 \pm 0.5\%$	$7.6 \pm 0.2\%$	↓
Post Intervention																	
Outcome measure	Control group (usual care)	Intervention group (PRT)	Results														
HbA1c	$8.3 \pm 0.5\%$	$7.6 \pm 0.2\%$	↓														
Maiorana et al (2002)²⁴	16 subjects (age 52 ± 2 years) with type 2 diabetes	Usual care/standard care	8-week circuit training (CT) program, combining aerobic and resistance exercise	3 one-hour sessions. 10-min warm-up/cool down and stretching period	<table border="1"> <tr> <td colspan="4">Post Intervention</td> </tr> <tr> <th>Outcome measure</th><th>Control group (usual care)</th><th>Intervention group (CT)</th><th>Results</th></tr> <tr> <td>HbA1c</td><td>$8.5 \pm 0.4\%$</td><td>$7.9 \pm 0.3\%$</td><td>↓</td></tr> </table>	Post Intervention				Outcome measure	Control group (usual care)	Intervention group (CT)	Results	HbA1c	$8.5 \pm 0.4\%$	$7.9 \pm 0.3\%$	↓
Post Intervention																	
Outcome measure	Control group (usual care)	Intervention group (CT)	Results														
HbA1c	$8.5 \pm 0.4\%$	$7.9 \pm 0.3\%$	↓														
Cuff (2003)²⁵	28 obese postmenopausal women (59.4 ± 1.9 to 63.4 ± 2.2 years) with type 2 diabetes	Usual care/standard care	16-week treatments: aerobic only training (Ae only), or aerobic plus resistance training (Ae + RT)	1. Ae + RT: 3 times per week. Each class consisted of a warm-up, an aerobic phase, a resistance training phase, and a cool down to total a class time of 75 min. 2. Ae only: 3 times per week, with 75-min structured exercise classes. Each class consisted of a warm-up, an aerobic phase, and a cool down	<table border="1"> <tr> <td colspan="4">Post Intervention</td> </tr> <tr> <th>Outcome measure</th><th>Control group (usual care)</th><th>Intervention group (CT)</th><th>Results</th></tr> <tr> <td>HbA1c</td><td>$-0.43 \pm 0.29\%$</td><td>Ae + RT: $-1.4 \pm 3.2\%$ Ae: $1.59 \pm 1.74\%$</td><td>↓</td></tr> </table>	Post Intervention				Outcome measure	Control group (usual care)	Intervention group (CT)	Results	HbA1c	$-0.43 \pm 0.29\%$	Ae + RT: $-1.4 \pm 3.2\%$ Ae: $1.59 \pm 1.74\%$	↓
Post Intervention																	
Outcome measure	Control group (usual care)	Intervention group (CT)	Results														
HbA1c	$-0.43 \pm 0.29\%$	Ae + RT: $-1.4 \pm 3.2\%$ Ae: $1.59 \pm 1.74\%$	↓														

Tessier (2000)²⁶	39 Candidates with type 2 DM between 65 years and Older	Usual care/standard care	16 weeks exercise intervention: aerobic physical exercise program	Each session comprised: a warm-up phase (10 min), a cardiovascular portion of rapid walk (20min), a strength/endurance portion consisting of two sets of 20 repetitions of major muscle groups (20 min) and finally, stretching exercises and relaxation (10 min)	Post Intervention			
					Outcome measure	Control group (usual care)	Intervention group (Aerobic)	Results
					HbA1c	7.8 ±91.5	7.6±91.2	↓
Sigal (2007)²⁷	251 adults aged between 39 to 70 years with type 2 diabetes	Usual care/standard care	22 Weeks Exercise training: Aerobic only (Ae), resistance only (RT) or combined exercise training (Ae +RT).	3 times weekly: 1. Ae only: Participants progressed from 15 to 20 minutes per session at 60% of the maximum heart rate to 45 minutes per session at 75% of the maximum heart rate, as determined by using a maximal treadmill exercise test. 2. RT only: performed 7 different exercises on weight machines each session, progressing to 2 to 3 sets of each exercise at the maximum weight that could be lifted 7 to 9 times. 3. Ae + RT : Full aerobic training program plus the full resistance training	Post Intervention			
					Outcome measure	Control group (usual care)	Intervention group (CT)	Results
					HbA1c	7.51±1.47	Ae:6.98±1.50 RT:7.18±1.52 Ae+RT:6.56 ±1.55	↓
Dunstan (2002)¹⁶	36 sedentary, overweight men and women with type 2 diabetes, aged between 60–80 years	control program (WL) stationary cycling with no workload for 5 min, followed by a series of static stretching exercises (30 min).	6-month resistance training (RT) intervention all subjects attended the exercise laboratory on 3. Resistance training consisted of a	3 non-consecutive days per week 5-min warm-up and 5-min cool-down period of Low-intensity stationary cycling and~45min of high-intensity resistance training (dynamic exercise involving concentric and eccentric contractions).	Post Intervention			
					Outcome measure	Control group (WL)	Intervention group (RT &WL)	Results
					HbA1c (%)	7.5 ± 1.1	6.9 ± 0.91	↓

Bweir (2009)²⁹	23 previously inactive patients between 45 and 65 years of age with type 2 diabetes	10 weeks of Aerobic/treadmill (Ae) exercise group.	10 weeks of Resistance training group.	<p>1.Ae: Participants progressed from 20 minutes per session at 60% of the maximum heart rate to 30 minutes per session at 75% of their maximum heart rate on treadmill</p> <p>2.RT: 7 exercises were used that encompassed knee and hip flexion/extension, shoulder flexion/extension, Adduction/abduction, elbow flexion/extension and a chest press, based on previous publications .3 sets of 8-10 repetitions were performed for all exercises.</p> <p>Subjects completed each exercise in a controlled rhythm, with a rest period of 2 minutes between sets.</p>	<table border="1" data-bbox="1477 255 2084 477"> <thead> <tr> <th colspan="4">Post Intervention</th> </tr> <tr> <th>Outcome measure</th><th>Ae group</th><th>RT group</th><th>Results</th></tr> </thead> <tbody> <tr> <td>HbA1c (%)</td><td>7.5 ± 1.1</td><td>6.9 ± 0.91</td><td>↓</td></tr> </tbody> </table>	Post Intervention				Outcome measure	Ae group	RT group	Results	HbA1c (%)	7.5 ± 1.1	6.9 ± 0.91	↓
Post Intervention																	
Outcome measure	Ae group	RT group	Results														
HbA1c (%)	7.5 ± 1.1	6.9 ± 0.91	↓														
Ibanez (2005)²¹	9 older men (aged 66.6 ± 3.1) with type 2 diabetes	Usual care/standard care	16-week PRT supervised program	<p>Two times per week for 45–60 min per session.</p> <p>Each training session included two exercises for the leg extensor muscles, one exercise for the arm extensor muscle and four to five exercises for the main muscle groups of the body. Only resistance machines (Technogym, Gambettola, Italy) were used throughout the training period.</p>	<table border="1" data-bbox="1477 774 2084 997"> <thead> <tr> <th colspan="4">Post Intervention</th> </tr> <tr> <th>Outcome measure</th><th>Control group</th><th>Intervention group</th><th>Results</th></tr> </thead> <tbody> <tr> <td>HbA1c (%)</td><td>6.2 ± 0.9</td><td>6.2 ± 0.9</td><td>No difference</td></tr> </tbody> </table>	Post Intervention				Outcome measure	Control group	Intervention group	Results	HbA1c (%)	6.2 ± 0.9	6.2 ± 0.9	No difference
Post Intervention																	
Outcome measure	Control group	Intervention group	Results														
HbA1c (%)	6.2 ± 0.9	6.2 ± 0.9	No difference														
Fritz (2006)²²	26 patients, aged 60.0 ± 7.3 years	Usual care/standard care	4 months brisk walking	Instructed to increase their exercise by 45 min of brisk walking, three times weekly, during 4 months.	<table border="1" data-bbox="1477 1084 2084 1291"> <thead> <tr> <th colspan="4">Post Intervention</th> </tr> <tr> <th>Outcome measure</th><th>Control group</th><th>Intervention group</th><th>Results</th></tr> </thead> <tbody> <tr> <td>HbA1c (%)</td><td>6.3 ± 0.9</td><td>6.3 ± 0.9</td><td>No difference</td></tr> </tbody> </table>	Post Intervention				Outcome measure	Control group	Intervention group	Results	HbA1c (%)	6.3 ± 0.9	6.3 ± 0.9	No difference
Post Intervention																	
Outcome measure	Control group	Intervention group	Results														
HbA1c (%)	6.3 ± 0.9	6.3 ± 0.9	No difference														

Arora (2009)²⁸	30 adults (14 females and 16 males mean; age 53.8 ± 8.8 yr) with type 2 diabetes	Usual care/standard care	8 weeks of progressive resistance training (PRT) and aerobic exercise (AE)	<p>PRT: 5 min warm up (static cycling) followed by seven exercises for major muscle groups-biceps, triceps, upper back, abdominals, knee flexors and extensors; 3 sets of 10 repetitions of each exercise per session. This was followed by 5 min cool down (static cycling).</p> <p>Ae: aerobic exercise for 30 min per day thrice a week for 8 wk.</p>	Post Intervention			
Outcome measure	Control group (usual care)	Intervention group (CT)	Results					
HbA1c	7.41 \pm 0.9%	Ae: 6.66 \pm 0.9% PRT: 6.23 \pm 0.8%	↓					

META-ANALYTIC CRITICAL REVIEW ON EFFECTS OF CONVENTIONAL PHYSIOTHERAPY IN MUSCLE STRENGTH

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ABSTRACT

This study intended to systematically review published research literatures to identify and evaluate the effectiveness of conventional physiotherapeutic (CP) training on improvement in muscle strength in middle-aged and elderly female individuals diagnosed as having Osteoarthritis (OA) of knee. Multiple databases having articles published between 2000 and 2016, such as - Web of Science, ProQuest, PubMed, Ebscohost and CINAHL were methodically searched for articles related to OA of knee. Only descriptive, meta-analytical and interventional research articles were retained. Overall effect size with 95% confidence intervals (CIs) was used to assess the strength of the relationship between interventions and improvement in muscle strength among elderly OA of knee patients, by using a random effects model. Heterogeneity was also evaluated. 9 experimental studies were selected and included in the review, out of which 4 were randomized controlled trials and rest were pseudo-randomised controlled trials. Studies considering drug co-interventions were excluded. Standardized effect sizes with 95% confidence interval (CIs) were calculated from the pre-intervention and post-intervention means of the conventional physiotherapy (CP) training group and other intervention or no-intervention group. A generalized performance Altogether nine articles were analysed for improvement in strength. Pooled analysis of the results from the articles included clarified that, out of nine articles, only three favoured CP training as a modality for improvement in muscle strength in elderly OA patients. Rest of the articles (six articles) were found to favour no-intervention condition. Thus, the beneficial impact of CP training in improving muscle-strength in OA patients, did not get confirmed. This finding recommends that further studies following rigorous methodology are required to derive definitive evidence to confirm the beneficial effects of CP training on improvement in muscle strength among elderly patients suffering from osteoarthritis of knee.

COMPETING INTERESTS:

Conflict of interest declared none.

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KEYWORDS: *Osteoarthritis, Conventional physiotherapy training, Muscle strength, Meta-analysis*

1. INTRODUCTION

Twentieth century life-style is comprised of extremely busy and hectic schedules coupled

with stressful target orientations and inconsistent routines for daily activities. These erratic life-style cannot provide ample opportunity for maintenance of healthy-living habits, which obviously may

lead to some ailments. When someone gets affected by illness, injury or disability, therapeutic interventions are required to assist in reducing level of discomfort and to rehabilitate in function and movement. Physiotherapy is one of such intervention technique, and there are strong documentary evidences to support the advantages of physiotherapy treatment in reducing pain, improving muscle strength and function in participants with knee OA.¹⁻² Conventional physiotherapy exercise treatment is one of such physiotherapy intervention comprised of exercise therapy, manual therapy or bodywork, electrotherapy, hydrotherapy, home exercise program and patient education. All of these are categorized as non-pharmacological treatments³. Manual therapy and exercise such as strengthening exercise, stretching exercise and range of motion exercise are included in the treatment of participants with knee OA⁴. Regular supervision, monitoring and motivation are necessary for long term compliance in knee OA participants⁵.

In the rehabilitation process for the knee osteoarthritis participants, physiotherapy plays a vital role. In the existing literature, impacts of different agents of physiotherapy and exercise forms for knee OA participants involving improvement in physical function, enhancement in range of motion (ROM) of knee joint, reduction of pain and improvement in muscle strength have been thoroughly discussed. These studies have carried out in depth analysis to find out the most effective protocol to treat the knee OA participants.^{6,1,7,8-10} This section of review illustrates the impact of different Conventional

Physiotherapy (CP) and electrotherapy modalities on knee OA participants.

Although, lots of studies have been conducted to evaluate the effectiveness of physiotherapy protocols on OA of knee, but introduction of CP exercises on knee OA patients and impact of those training regimes in strengthening muscles, and in enhancing mobility in OA patients have so far been neglected. This study based on meta-analytical systematic review of reported literatures, purports to evaluate impact of CP in strengthening muscle among middle-aged and elderly individuals diagnosed as suffering from OA of knee.

2. META-ANALYSIS ON THE OUTCOME OF CONVENTIONAL PHYSIOTHERAPY IN KNEE OA

A meta-analysis has been carried out to assess the impact of Conventional Physiotherapy in knee OA. Explanation of Meta-analysis process has been discussed below.

2.1 Search Strategy

Existing published literature (2006 to 2015) and online sites such as Web of Science, ProQuest, PubMed, Ebscohost and CINAHL were thoroughly searched for this analysis. The terms such Conventional Physiotherapy OR physiotherapeutic exercises OR Conventional Physiotherapy in knee osteoarthritis OR physiotherapy in knee osteoarthritis OR exercise in knee osteoarthritis have been used in search strategy (Table 1). Cross-referencing was also done to find out articles related to this review.

Table 1
Search Strategy

Databases	Search Items
Web of Science, ProQuest, PubMed, Ebscohost and CINAHL	The following terms as words within the title, abstracts or text of research literatures: <ul style="list-style-type: none"> ➤ “Physiotherapy”, “exercises”, “osteoarthritis”, “knee osteoarthritis” and “exercise in knee osteoarthritis”. ➤ “Conventional Physiotherapy”, “physiotherapeutic exercises”, “Conventional Physiotherapy in knee osteoarthritis”, “physiotherapy in knee osteoarthritis” and “exercise in knee osteoarthritis” as words within the title, abstracts or texts of papers.

Selection process for the articles has been depicted by the PRISMA flow diagram (Figure 1)

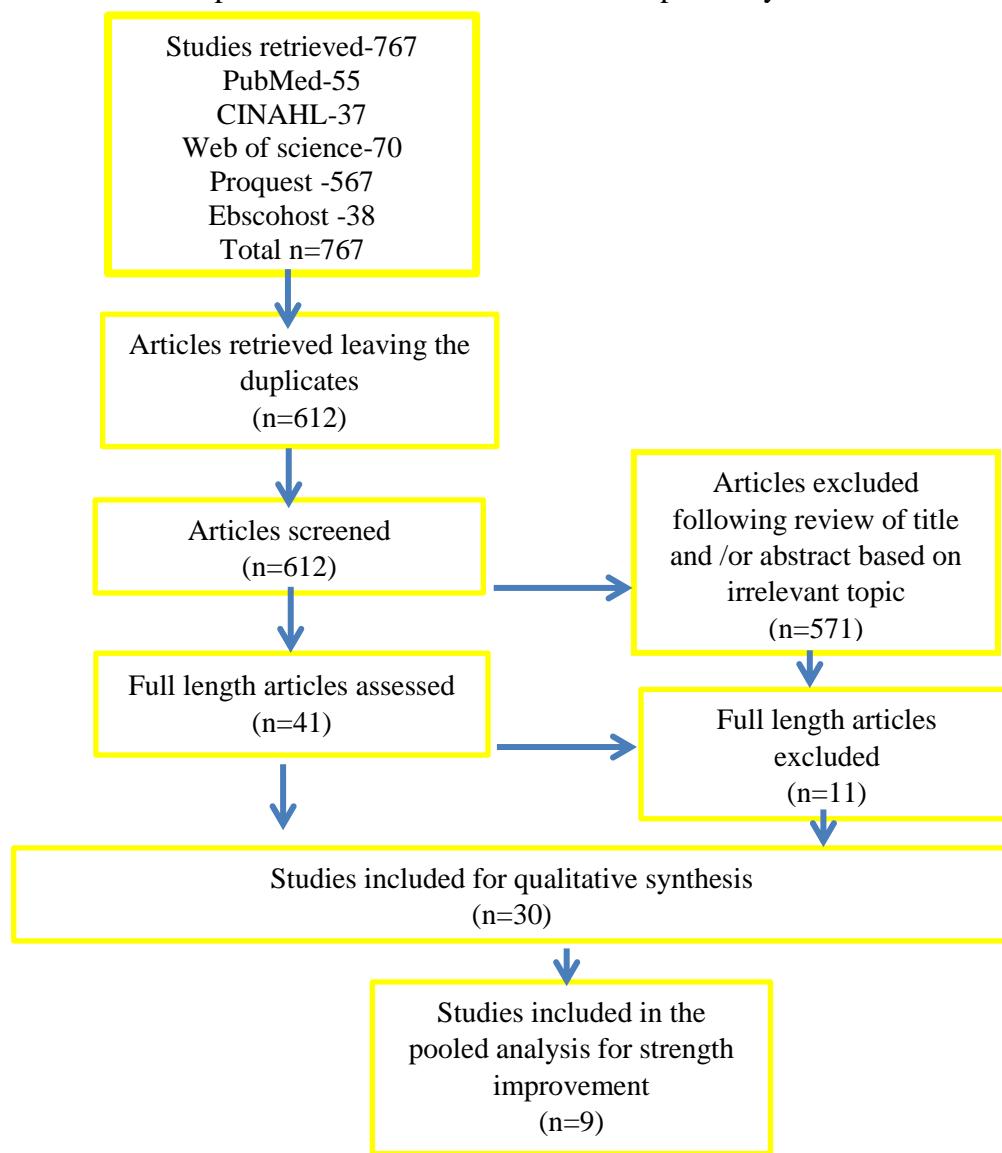


Figure 1
PRISMA Flow Diagram

2.2 Inclusion Criteria:

The criteria for the study to be included in the review as follow:

- i. Studies included Conventional Physiotherapy to treat participants with knee OA.
- ii. Only Conventional Physiotherapy and a comparative exercise and / or any other intervention to improve muscle strength and physical function for knee OA participants.
- iii. Participants with knee OA.
- iv. Included studies were required to assess the changes in muscle strength.

- v. Articles published between 2006 to 2015 and in English language were taken into account.

2.3 Methodological Quality Assessment:

Physiotherapy Evidence Database (PEDro) scale has been used to assess the methodological quality of all the articles that were included in this review. This is a widely used tool to evaluate the methodology of the studies and it consists of 11 – point scale. The PEDro scores are shown below (Table 2).

Table 2
PEDro Scores of the Trials

Study	1. Eligibility criteria?	2. Random allocation?	3. Concealed allocation?	4. Baseline Similarity?	5. Blind participants?	6. Blinding therapists?	7. Blinding assessors?	8. Follow up?	9. Intention to treat analysis?	10. Group comparison?	11. Point and variability?	Score
Sham et al., 2015	✓	✓	x	✓	x	x	x	x	✓	✓	x	5/11
Anwer et al., 2014	✓	✓	x	✓	x	✓	x	x	✓	✓	x	6/11
Ju et al., 2015	✓	✓	x	✓	x	x	x	x	✓	✓	x	5/11
Swank et al., 2011	✓	✓	x	✓	x	x	x	x	✓	✓	✓	6/11
McKay et al., 2012	✓	✓	x	✓	x	x	x	✓	✓	✓	x	6/11
Mikesky et al., 2006	✓	✓	x	✓	x	x	✓	x	✓	✓	✓	7/11
van Leeuwen et al., 2014	✓	✓	✓	✓	x	x	✓	x	✓	✓	✓	8/11
Lim et al., 2008	✓	✓	✓	✓	x	x	✓	x	✓	✓	✓	8/11
Chaipinyo et al., 2009	✓	✓	✓	✓	x	x	✓	x	✓	✓	✓	8/11
Score	9/9	9/9	3/9	9/9	0/9	1/9	4/9	1/9	9/9	9/9	5/9	5.95

✓-Yes; x-No

2.4 Statistical Analyses

In this meta-analysis post intervention means and standard deviations were gathered for groups having Conventional Physiotherapy intervention. Calculations of Standardised effect sizes at 95% Confidence intervals were carried out. The results of different studies were compared with standardised effect sizes. According to Cohen¹¹, effect sizes were categorized as weak ($d \leq 0.2$), small ($d = 0.2-0.5$), moderate ($d = 0.5-0.8$) and strong ($d \geq 0.8$).

2.5 Results and Discussion

In this review nine studies consisting of 278 knee OA participants were included. The included studies had a good score in methodological quality with an average of 5.95, with the highest score of 8^{9,12-13} and the lowest was 5.^{1,14}

Table 3
Demographic Characteristics of the Trial

Researcher	Diagnosis	Age	Population	Male /female	Outcomes
Shyam et al., 2015	Knee Osteoarthritis	65-85	80	NA	Pain, Isometric quadriceps strength, Knee function.
Anwer et al., 2014	Knee Osteoarthritis	40-65	42	13/29	Pain, Isometric quadriceps strength, Knee function.
Ju et al., 2015	Knee Osteoarthritis	65.7 ± 3.5	14	0/14	Knee joint muscle function, pain (VAS).
Swank et al., 2011	Knee Osteoarthritis	63	71	25/46	Pain, Strength, Function.
McKay et al., 2012	Knee Osteoarthritis	63.5 ± 4.93	22	NA	Isometric quadriceps strength. Mobility, Pain, Self-reported function, Health-related quality of life, Arthritis self-efficacy.
Mikesky et al., 2006	Knee Osteoarthritis	69	221	93/128	Pain, Functional limitation, Strength, General health status and depression scores.
van Leeuwen et al., 2014	Knee Osteoarthritis	Above 55	22	12/10	Feasibility, Strength, Functional tasks, Relationships between quadriceps strength and physical performance.
Lim et al., 2008	Knee Osteoarthritis	67.2 ± 6.7	107	48/59	Knee adduction moment, Pain and physical Function (WOMACS), Step test score, Stair climb test score, Maximum quadriceps isometric strength.
Chaipinyo et al., 2009	Knee Osteoarthritis	Above 50	48	11/37	Pain, Function in daily living, Function in sport and recreation, Knee-related quality of life, Strength, Mobility.

NA- Not Available

Table 4
Characteristics of Intervention of the Included Trial

Researcher	Device	Contraction	Repetitions
Shyam et al., 2015	NA	Isometric quadriceps exercise and Straight leg raising (SLR) exercise	10 repetitions for all the exercises. In the first week participants carried out 1 set of exercises for 2 times per day and gradually the intensity of exercise protocol increased to 2 sets 2 times a day till the third week.
Anwer et al., 2014	Ultrasound therapy, Plinth, Towel, Small pillow	Isometric quadriceps exercise (held for 5 seconds), Straight leg raising (SLR) with leg 10 cm lift and held for 10 seconds, Isometric hip adduction exercise (held for 5 seconds)	10 repetitions for all the exercises. In the first week participants carried out 1 set of exercises for 2 times per day and gradually the intensity of exercise protocol increased to 3 sets 2 times a day till the fifth week.
Ju et al., 2015	Jumper, Aero-step, IseMed 2000	Proprioceptive circuit exercise- half squat, straight lunge, side lunge, and one-legged balance exercise	10 times for 3 sets
Swank et al., 2011	Thera-Band bands	Resistance training using bands, Flexibility, and Step training start with warm up Squat, leg extension, leg curl, hip adduction, hip abduction, hip flexion, hip extension, foot plantarflexion, foot dorsiflexion, Step ups forwards/lateral both side, cool down.	All the exercises performed with low resistance, 10 times for 1 set at week 1 and 2 then progress to 2 sets at week 3 and 4. The same protocol were performed at week 5 until week 8 with moderate resistance.
McKay et	Treadmill,	Warm-up session for 10 minutes either by using	Bilateral lower body exercises and

al., 2012	cycling ergometer, rowing ergometer, or recumbent stepper.	stepper, treadmill, rowing ergometer or bicycle ergometer for the experimental group. After that the participants of the experimental group performed exercises for bilateral lower body which included, seated leg press, knee extension exercise, leg curl and standing calf raise. The control group of this study carried out warm-up session for 10 minutes same as the experimental group, followed by exercises for bilateral upper body which included elbow extension and flexion exercise, chest press exercise and latissimus dorsi exercise in sitting position.	bilateral upper body exercises – with 8 repetitions for 2 sets.
Mikesky et al., 2006	Cybex, elastic bands	Warm-up and cool-down session, resistance exercises consisted of seated rows, wall squats, standing leg curls, leg presses, seated chest presses, leg curls, wall pushups and seated back rows. Flexibility exercises involved the whole body	Resistance training – 8 to 10 times for 3 sets and progress to 2 times for 2 sets. Participants need to perform 10 times every exercise in flexibility training.
van Leeuwen et al., 2014	Dumbbells or plates	Therapy consists of aerobic exercise, resistance exercise, training of walking with aids, activities of daily life training, information and advice, and maintenance of mobility.	Resistance training- 15 times for 3 sets Squat exercise and home program – 2 to 3 sessions/week.
Lim et al., 2008	Ankle weight sand, Thera-Band	Quadriceps strengthening exercises (Isometric knee extension at 60 degrees' knee flexion, Inner range knee extension, Straight leg raise, Long arc knee extension and Isometric knee extension at 30 degrees' knee flexion).	First 2 weeks' participants need to perform 10 times for 2 sets and progress to 3 sets until the week 12.
Chaipinyo et al., 2009	--	Balance group- stepping forward and backward than sideways for each leg and bilateral mini squat (15-30 degrees of knee flexion). Strength group- isometric knee extension in sitting for each leg hold for 5 seconds, 5 days per week.	30 times for stepping forward and backward than sideways for each leg, bilateral mini squat and isometric knee extension.

NA- Not Available

3. DISCUSSION BASED ON PEDro SCORES ANALYSIS, DEMOGRAPHIC AND FOREST PLOT ANALYSIS

Here regarding the quality of the systematic reviews and definitely concerning the RCTs included in this review, questions may be raised. Here we need to clarify that, as per the guidelines of National Health and Medical Research Council¹⁵, the experimental studies we included in this review were considered, only after identification of satisfactory level or strong evidence. Aforementioned guidelines provided us enough opportunity evaluate the extent of authenticity of the evidence obtainable in the included studies. First of all, for inclusion of the studies it was required to check, whether the studies were properly designed and those were carried out following rigorous methodology or not. Furthermore, RCTs included were also checked with the criterion based on whether those were properly controlled randomized controlled

trials (RCT) or pseud-randomized controlled trials (PRCT); or controlled clinical trials (CCT); or only non-randomized clinical trials (NRCT). For evaluation of validity and authenticity of the experimental studies included in this review, the best evidence synthesis technique¹⁶ was followed. Earlier for evaluation of criterion for grading of evidences, Hillier and colleagues¹⁷ employed the standardized format of analysis (PEDro Scale – Physiotherapy Evidence Database)¹⁸ of quality of RCTs. As per their recommendations, experimental studies evident as scoring more than 4 points out of 11 (i.e., PEDro Scale scores), are supposed to be considered as high-quality studies.¹⁷ Thus, for final analyses, 2^{1,14} out of 9 studies were observed to have grade - III-2 level of evidence; while 3 others^{7-8,19} were evident to fall under grade - III-1 level of evidence.

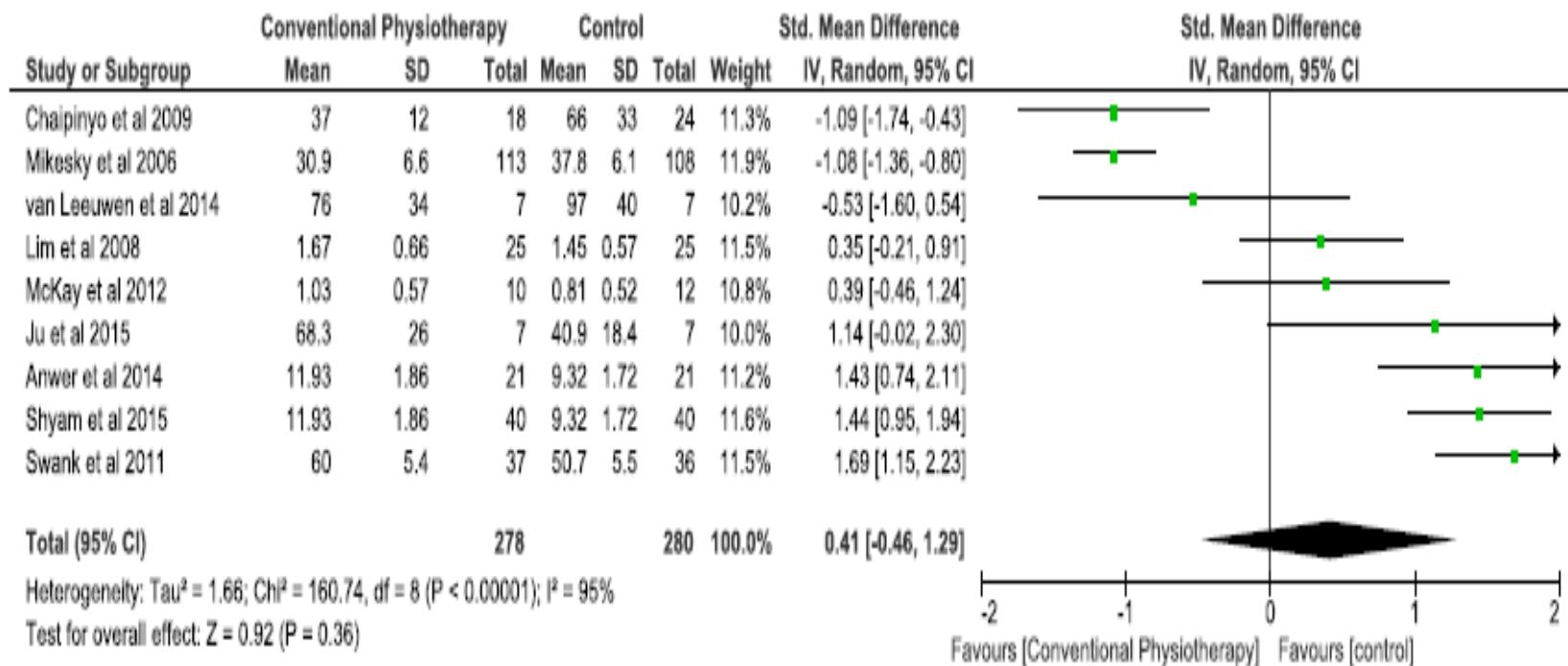


Figure 2
Forest Plot Depicting Effects of Conventional Physiotherapy in Muscle Strength

Thus, for final analyses following the criteria of demarcation, PEDro Scale¹⁷ evaluations and Remaining 4 studies^{9,12-13,20}, however were identified as having Grade II category of strong evidence. Apart from that, two studies^{1,14} were evident to receive PEDro Scale quality score 5 out of 11 and three other studies^{7,8,19} received PEDro Scale quality score 6 out of 11. Hence, as far as Hillier and colleagues¹⁶ recommended, these studies are supposed to be considered as high-quality studies, having high strength of evidence.¹⁶ Apart from that, studies conducted by van Leeuwen and coresearchers⁹; Lim and colleagues¹² and Chaipinyo and coresearchers¹³, were observed to achieve PEDro scores 8, while the study of Mikesky et al.²⁰ received a score of 7 out of 11. Thus, these studies revealed moderately high level of authentic quality of evidence (refer to Table 2). To sum up it may be postulated that the outcomes of this study indicated beneficial impact of the conventional physiotherapy training regimes in improving muscle strength among elderly and middle-aged both female and male individuals diagnosed with OA of knee.

4. DISCUSSION BASED ON CONTENTS OF DEMOGRAPHIC AND INTERVENTION CHARACTERISTICS

In this review nine studies consisting of 278 knee OA participants were included. The included studies had a good score in methodological quality with an average of 5.95, with the highest score of 8^{9,12-13} and the lowest was 5.^{1,14} All the included studies had different protocol for intervention techniques (Table 3 & 4). McKay et al.⁸ for instance recruited their participants, who were imparted with bilateral lower body exercises and bilateral upper body exercises – with 8 repetitions for 2 sets. Contemporarily, van Leeuwen et

al.⁹ on the other hand, introduced resistance training for 15 times/set for 3 sets; which included squat exercises and home exercise programs for 2 to 3 sessions/week. While Chaipinyo et al.¹³ subjected their participants for stepping forward and backward for 30 times, and thereafter the same task sideways for each leg, along with bilateral mini squat and isometric knee extension activities as well.

Then in the study done by Shyam et al.¹ the experimental group received isometric training consisting of isometric hip adduction training, straight leg raising (SLR) and quadriceps isometric exercise. All the exercises were done for 10 repetitions. In the first week, participants carried out 1 set of exercises for 2 times per day and gradually the intensity of exercise protocol increased to 2 sets 2 times a day till the third week. Finally, participants performed 3 sets 3 times a day till the end of the intervention. At the end of the study, it was found that, strengthening exercises have the possibility to reduce the pain level and disability and enhance the peak muscle torque in knee OA participants.

McKay and his colleagues⁸ followed the protocol starting with warm-up session for 10 minutes either by using stepper, treadmill, rowing ergometer or bicycle ergometer for the experimental group. After that the participants of the experimental group performed exercises for bilateral lower body which included, seated leg press, knee extension exercise, leg curl and standing calf raise for 2 sets of 8 repetitions. On the other hand, the control group of this study carried out warm-up session for 10 minutes same as the experimental group, followed by exercises for bilateral upper body which included elbow extension and flexion exercise, chest press and latissimus dorsi exercise in sitting position for 2 sets of 8 repetitions. At the end of the study there were beneficial impacts on enhancing strength in quadriceps, mental health and speed of walking prior to surgery.

In this review the overall effect size for the effects of Conventional Physiotherapy in muscle strength was 0.41 with a confidence interval of -1.46, 1.29. The heterogeneity of the included studies was 96% which is considered to be very high in the context of clinical trials. The χ^2 value is about 160.74 (P=0.001) with degrees of freedom of 8. The differences in the outcome of the studies were subject to number of participants, intervention protocol, co-intervention processes and others. So, all these factors led to extremely high level of heterogeneity of the studies reviewed. From this analysis it can be seen that, as majority of the researchers viewed it, Conventional Physiotherapy did not have any impact in improving the muscle strength for knee OA participants. Nevertheless, with scanty relevant data, it is difficult to conclude that Conventional Physiotherapy does not have any effects on muscle strength based on wide range of 95% confidence interval and effect sizes. Therefore, it can be stated that based on the literature reviewed, Conventional Physiotherapy may not convincingly lead to the improvement and enhancement of the muscle strength of knee for participants facing problems with knee OA. Yet this conclusion may differ if further studies are incorporated in the meta-analysis.

To sum up it can be said that impact of Conventional Physiotherapy for treating knee OA participants could be favourable in reducing their pain level and improving their physical functions. But, effect of conventional exercise therapy on improving muscle strength in knee OA participants is debatable. It is important to mention that there was limited number of researches investigating the impacts of Conventional Physiotherapy on changes in muscle-strength knee OA. Therefore, the results for the Conventional Physiotherapy might get altered if other related studies are included for meta-analysis in future.

5. LIMITATIONS OF THIS REVIEW AND INCLUDED STUDIES

This study suffers from a few limitations, as only nine studies were included and as all of the studies were not having high or moderately high-quality evidences. Few of the studies did not provide the mean differences, and hence it was difficult to include those studies in meta-analysis, as without those, meta-analytic Forest-plot evaluation would not be performed. Apart from that, the Forest-plot itself depicted that, only three studies out of nine favoured conventional exercise regimes, while other studies favoured other treatment protocols. Thus, it was difficult to analyse the efficacy of the conventional exercise interventions in improving muscle-strength among elderly and middle-aged individuals suffering from OA of knee. Owing to our strict inclusion criteria, we had to exclude lots of the studies and articles. Since the search was restricted to articles published in English only, the activity and participation issues reported here may not be universal.

6. CONCLUSIONS

Though scanty, a group of authentic systematic reviews and good number of RCTs with strong evidence have revealed that quite a few of elderly and middle-aged individuals diagnosed as suffering from OA of knee, could achieve success in improving their muscle-strength by virtue of conventional physiotherapy exercise training. Realistically viewing the outcome of this review, it could be clarified that, majority of the studies included favoured other therapeutic assistances better than the conventional physiotherapy exercise regimes. This study from within its limitations highlighted the role of exercise programmes. Furthermore, it emphasized that, the exercise trainings if imparted following rigorous methodology,

those would lead to major gross-motor functional improvements, and consequent reduction of crises pertaining to OA of knee, among Malaysian elderly individuals. We hope that the findings of this study will be useful to orthopaedists, neuro-orthopaedists, teachers, physiotherapists and exercise therapists working with elderly and middle-aged individuals, especially female individuals suffering from OA. This study will enable the therapists, and researchers in improving the quality of movement performances and quality of life, as well as encourage future researchers to carry out more systematic reviews and RCTs to enrich this field of study.

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8. CONTRIBUTION OF AUTHORS

Conceived and designed the experiments: SrS, SoS, AaS, NbR
 Collected data and performed the experiments: CmL, NbR, SoS
 Contributed with materials/analysis tools: SrS, SoS, AaS, NbR
 Analyzed the data: SrS, SoS, NbR
 Wrote the paper: SoS, SrS, NbR
 Checked and edited the format of the paper: SrS, SoS, AaS, NbR
 Final approval: SrS, SoS, AaS, NbR

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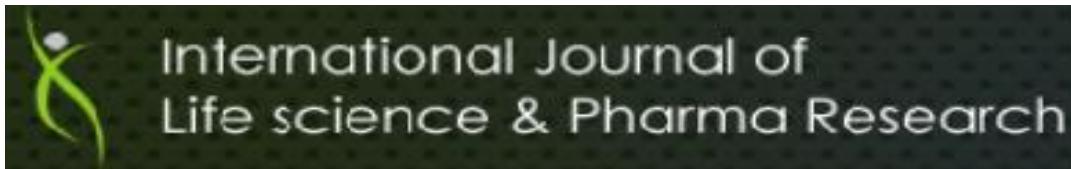
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BEHAVIOURAL INTERVENTIONS TO REDUCE THE LEVEL OF HBA1C FOR EFFICIENT AND EFFECTIVE MANAGEMENT OF TYPE 2 DIABETES MELLITUS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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COMPETING INTERESTS:
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ABSTRACT

This review was carried out to find out the effects of behavioural interventions to reduce the level of HbA1c for efficient and effective management of Type 2 Diabetes Mellitus (T2DM). PubMed, EMBASE and Science Direct and other electronic databases were searched for the published literature. Overall effect size with 95% confidence intervals (CIs) was used to assess the strength of the relationship between interventions and T2DM by using a random effects model. Heterogeneity was also evaluated. 3 randomized controlled experimental studies were selected and included in the review. Studies considering drug co-interventions were excluded. Overall estimate of the mean differences of the behavioural interventions showed that the overall effect size for reduction in HbA1c was about -0.47 with a 95% confidence interval (CI) of -0.79 -0.15 and the I^2 value is 56%. Behavioural interventions were moderately effective in reducing the level of HbA1c to manage type 2 diabetes effectively.

KEYWORDS: *Type 2 Diabetes Mellitus; HbA1c; Behavioural Interventions; Meta-Analysis*

1. INTRODUCTION

The global prevalence of diabetes has been estimated as 415 million in 2015 and by the year 2040 this number may rise to 642 million as projected by the International Diabetic Federation (IDF).¹ Type 2 diabetes mellitus (T2DM) is the most common type of diabetes, accounting for around 90% of all cases of diabetes.² T2DM is most commonly seen in older adults, but it is increasingly seen in children, adolescents and younger adults due

to rising levels of obesity, physical inactivity and poor diet.¹ Regarding maintaining T2DM efficiently, the level of blood glucose or glycemic status needs to be monitored constantly along with regular involvement in physical activity and exercises.³⁻⁶ In connection to that self-regulatory interventional attempts and role of behavioural interventions have become vital as these interventions are generally aimed at providing patients with the coping skills and strategies required to promote and change their behaviour to manage the disease.⁷ In the diabetes literature, these

behavioural interventions are referred as self-management support interventions, and hence these are getting a sense of appreciation in the arena of diabetes management.⁷ The term ‘self-management’ however, is often confusing as there is no universally accepted definition and it is often used interchangeably with other concepts such as self-care, self-management training, patient empowerment, and self-management education.⁸ In modest terms, self-management can be described as what the patients themselves perform or manage on their own. Whereas, self-management support can be defined as what is provided as care by the health professional, as systematic guidance for behavioural practice.⁹ Therefore, it is imperative to understand that behavioural interventions are now also essential to manage the persistently increasing percentage of T2DM in all over the world.

Under this circumstance, it was intended to study the impacts of behavioural interventions on T2DM. We acknowledge the role of coping skills and strategies; self-regulation skills; dispositional attributes in stress- related crisis management as life-style skills in facilitating behavior modification towards effective metabolic regulation. Behavioural intervention aspects are heterogeneous in terms of content, implementation, and effectiveness. Interventions may differ on a range of dimensions, from behavior modification techniques used to encourage change to training of goal setting; intervention service delivery (e.g., frequency and duration of contact; one-to-one vs. group sessions).

Hence, the objective of this review is to pull together all relevant existing evidence that evaluate behavioural intervention to manage the burden of T2DM by reducing HbA1c level in type 2 diabetic patients.

2. MATERIALS AND METHOD

2.1 Search strategy

A search was conducted in the databases available in PubMed, Google Scholar, Scopus, Cochrane, EMBASE and Science Direct, using variations of the search string contained in Table 1. We searched into the aforementioned databases for randomized controlled trials (RCTs) that compared standard or usual care with behavioural interventions, facilitating desirable changes in lifestyle. The following terms were used in the search: diabetes, type 2 diabetes, HbA1c, impaired glucose tolerance, metabolic distress, self-care, self-management, lifestyle, health education, and behavioural intervention. In this review, articles from 2000 to 2015 were included. Studies published in languages other than English were excluded. RCTs that included drug and nutritional co-interventions, were also excluded. Further to that, the studies which were not randomized trials, did not have patients with T2DM, or did not investigate interventional programs relating to behavioural aspects, were also excluded from analysis.

Table 1
Search Strategy

Databases	Search Items
PubMed, Google Scholar, Scopus, Cochrane, EMBASE and Science Direct	<p>The following terms as words within the title, abstracts or texts of papers:</p> <p>(1) “health”, “diabetes”, “type 2 diabetes,” “impaired glucose tolerance,” and “metabolic distress”.</p> <p>(2) “lifestyle” or “health education” or “behavior intervention” as words within the title, abstracts or texts of papers</p>

2.2 Study selection and Screening

The selection criteria set for this review followed five specified characteristics of studies. First, the searches of the studies were accomplished within 31st December 2015, and were limited to Randomized Controlled Trials (RCTs) of at least satisfactory level of evidence, published in English language. Secondly, targeted population of the RCTs were specified only for patients diagnosed with T2DM. Third, the studies had to evaluate any category of behavioural intervention with a control group of patients with type 2 diabetes to manage T2DM. Finally, those studies evaluated at least one of the following outcomes: Glycated haemoglobin (HbA1c, A1C, or Hb1c; sometimes also HbA1c or HGBA1C), and sense of physical well-being and reported means and respective dispersion values of outcomes at post intervention of the intervention and control groups.

The screening process was carried out in four stages. Firstly, all articles were first screened on the basis of the titles and abstracts. Secondly, the screened and short-listed articles were thoroughly read. Thereafter, the reference lists of the short-listed articles were also screened. Lastly, in the fourth and last step, based on the aforementioned selection criteria for this review, final screening from the short-listed articles was carried out.

2.3 Data Extraction

At first studies were screened for compatibility by one author (FS) based on the selection criteria by their key words, titles and abstracts. Two other authors (SS & SS) once again independently screened the titles and abstracts of articles. After that, all of the authors assessed the selected materials independently in a standardized manner. All the findings were compared, and

differences were resolved by consensus among three authors. After that full texts of the studies were reviewed at length, with disagreements resolved via discussion amongst the authors. A standard review form was used to extract data from those studies, which included the name of the first author; year of publication; number of participants; age and gender of the participants; comparators used; intervention regimes incorporated in the study/control group, and results.

2.4 Comparators Used

In determining the effects of exercise interventions and behavioural interventions for T2DM, the choice of comparators against which the interventions are assessed, play a vital role. In this regard, studies included could be categorized in two parts. In first part, the studies were included, which assessed behavioural intervention against “usual care or standard health care”. In these studies, impacts of behavioural intervention were compared to situations where usual/standard care treatments were provided to the subjects by the general physicians or by themselves. In other cases, studies compared the impact of exercise intervention to an alternative intervention scenario where participants would be forced to obtain the intervention through alternative procedure.

2.5 Methodological Quality Assessment

Methodological quality of all included studies was evaluated with the help of Physiotherapy Evidence Database (PEDro) scale.¹⁰⁻¹¹ This scale consists of 11- point scale to evaluate the methodological issues of studies. Researchers have used PEDro widely as a critical appraisal tool.¹⁰⁻¹¹

Table 2

Methodological assessment of behavioural intervention studies with Physiotherapy Evidence Database (PEDro) scores

Study	1. Eligibility criteria?	2. Random allocation?	3. Concealed allocation?	4. Baseline Similarity?	5. Blind participants?	6. Blinding therapists?	7. Blinding assessors?	8. Follow?	9. Intention to treat analysis?	10. Group comparison?	11. Point and variability?	Score
Whittemore (2004)	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	7/11
Deakin (2006)	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No	6/11
Olivarius (2001)	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8/11
Score	10/10	10/10	0/10	10/10	0/10	0/10	8/10	10/10	10/10	10/10	9/10	6.2

2.6 Risk of Bias Assessment

Risk of bias assessment was conducted using Physiotherapy Evidence Database (PEDro) scale¹⁰⁻¹¹(Table 2). This scale is used for quality assessment and as a tool for risk bias assessment as well. This scale consists of 11- point scale to evaluate the risk bias. The assessment indicated that, for behavioural intervention studies, majority of the studies were identified as having low risk of bias.

2.7 Statistical Analyses

In this review, for Meta-analytical analysis we have used Review Manager 5.3 software (RevMan v5.3), in which means and standard deviations of the post intervention state of selected studies were taken into consideration for the participants of both the intervention and control/usual care groups. 95% confidence intervals and standardized effect sizes were calculated. The standardized effect sizes allowed us to compare the results among different studies. The data were separated based on the outcomes of HbA1c. Effect sizes were classified as weak ($d \leq 0.2$), small ($d = 0.2-0.5$) moderate ($d = 0.5-0.8$) and strong ($d \geq 0.8$).¹²

3. RESULTS

3.1 Literature Search

Based on the electronic database search strategy, 66 potentially relevant studies were identified by initial literature search and searches of reference lists. Thereafter 10 of the studies were excluded for duplication. Among the remaining studies, 56 studies met the criteria for data extraction requirements and had sufficient information to be included in this review and the rest of the studies were excluded from the review process. Then 10 records were thoroughly assessed based on the eligibility criteria and out of that, 3 studies were selected and included in the review. A flow diagram of the process of selection is shown in Figure 1. Brief characteristics of studies on behavioural interventions included in this review are illustrated in appendix.

3.2 Methodological Quality

Every article was assessed based on 11-point PEDro scale.^{3,11} The average score of the behavioural intervention studies was 6.2; where the highest score was 8 and the lowest score was 6. Among the selected studies, most of the studies did not score on blinding participants, therapists and assessors (Table 2).

3.3 Demographic Characteristics and Outcome Measures

The RCTs included in this study were evident as having heterogeneity in the number of participants in the research. The maximum number of participants for the behavioural intervention studies was observed as 970 and the minimum number of participants recruited was 53. There existed a lot of inconsistency in the ratio of sex of the participants (male and female) included, since most of the studies recruited larger number of

female participants. The primary outcome measure reported in all the studies were HbA1c (see appendix). The scanty database of behavioural intervention studies revealed a mixed impression, since the study of Whittemore¹³ revealed no post-intervention modification in the level of HbA1c, while other studies demonstrated beneficial impacts of behavioural interventions on the level of HbA1c and confirmed improved sense of wellbeing among the participants.

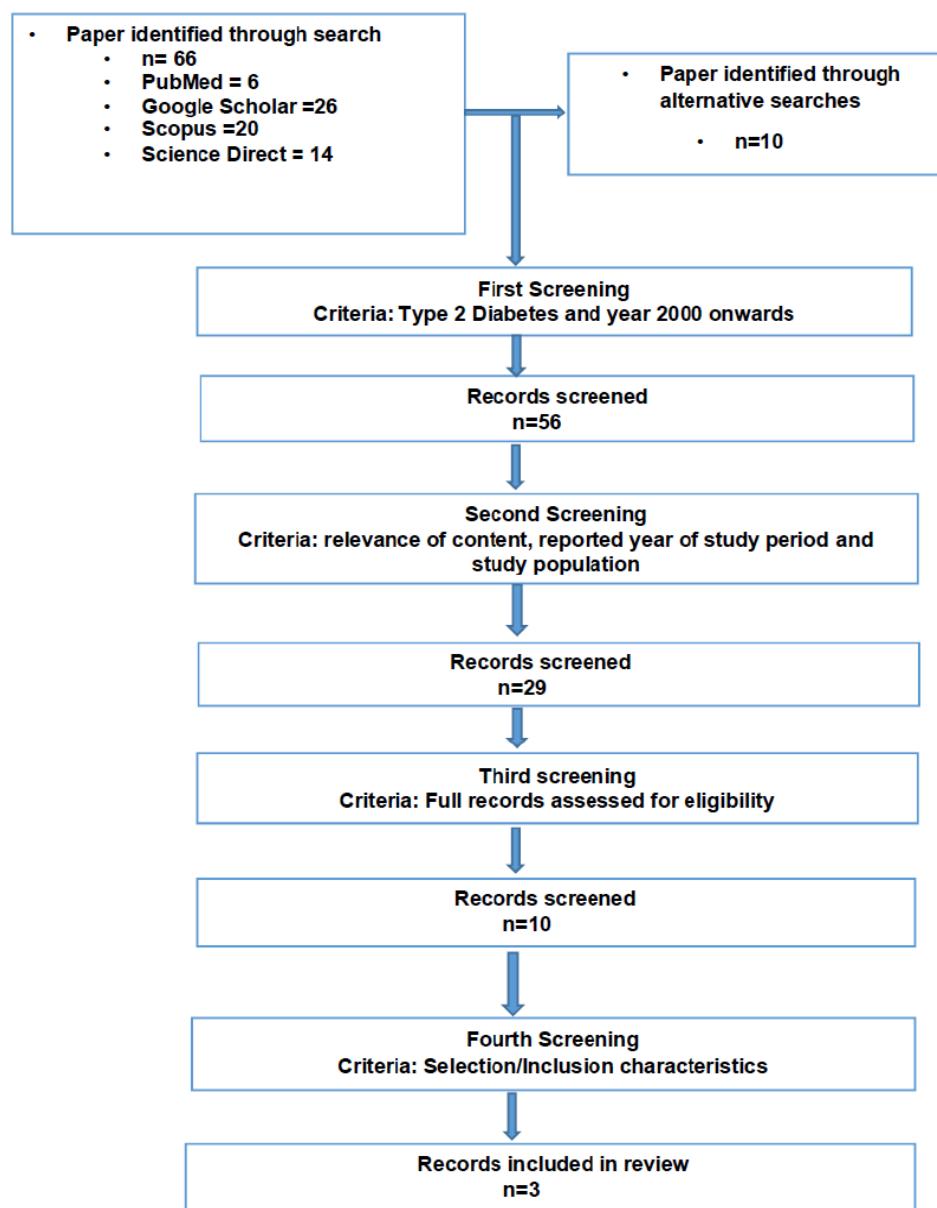


Figure 1
PRISMA Flowchart

3.4 Pooled Analysis

Behavioural interventions showed a homogenous, negative effect under the standardized mean difference analyses of the effect sizes for the

outcome of HbA1c for T2DM patients. The details of the effect size and 95%CI for exercise interventions are shown in Table 3.

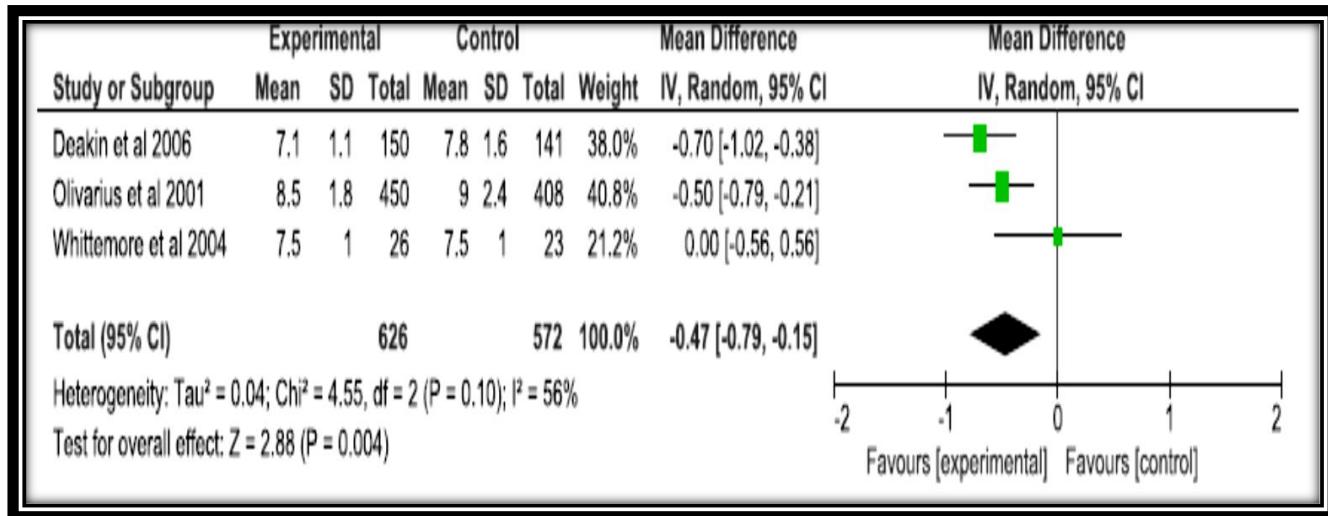
Table 3
Behavioural interventions' effects on HbA1c outcomes

Researcher	Behavioural Intervention	Usual care/ Standard care	Std. Mean Difference 95% CI		
			IV	Lower	Upper
Whittemore et al (2004)	7.5±1.0 (26)	7.5±1.0 (23)	0.00	-0.56	0.56
Deakin et al (2006)	7.1± 1.1 (150)	7.8 ± 1.6 (141)	-0.70	-1.02	-0.38
Olivarius et al (2001)	8.5 ± 1.8 (450)	9.0 ± 2.4 (408)	-0.50	-0.79	-0.21

Pooled analysis of the mean differences showed that the overall effect size for improvement in HbA1c due to behavioural interventions was about -0.47 with a 95% confidence interval (CI) of -0.79; -0.15 (Figure 2). The I^2 value of 56% suggests

slender heterogeneity of the studies. Out of the 3 studies, only 1 study¹³ did not favor behavioural interventions as effective measures in dipping the level of HbA1c among the T2DM patients.

Figure 2
Standardized mean difference analysis for behavioural interventions' studies



4. Discussion

In this review it has been seen that behavioural interventions conducted to manage T2DM in populations are efficient and successful to produce a moderate reduction in HbA1c levels in patients with T2DM compared with usual care.¹³⁻¹⁵

Like other chronic illnesses, management of diabetes is characterized by extensive patient involvement in addition to physician support. Specifically, there is an enormous demand on patients to manage the physical, emotional and psychological aspects of living. They are expected to follow an intense process of behavioural self-

regulation through diet, exercise, self-monitoring of blood glucose, foot care, and meticulous and sincere engagement during medical appointments. Patients' ability to manage their disease is influenced by a range of factors including social, environmental and individual variables. Despite differences in individuals' needs for coping with diabetes, Deakin and colleagues¹⁴ and Olivarius and the co-researchers¹⁵ have shown that, statistically significant improvements have been made by a patient-centered, group-based self-management program based on theories of empowerment and discovery learning. Further to that, as Whittemore et al¹³ hinted upon, though no significant changes between the usual care and behavioural intervention group in reducing the level of HbA1c was observed, but participants of both the groups evidenced improvements in managing the T2DM phenomenon.

Statistically, behavioural interventions showed results favoring the experimental group to manage T2DM. Pooled analysis of the mean differences showed that the overall effect size was about -0.47 with a 95% confidence interval (CI) of -0.79; -0.15 (Figure 2). The I^2 value of 56% suggested slender or moderate level of heterogeneity between the studies, which could be attributed wide range of variation on the sample size evident in different studies.¹⁶⁻¹⁷

However, a definitive evidence those behavioural interventions are effective enough in reducing the level of HbA1c for effective and efficient management of T2DM cannot be concluded as the interpretations of the findings related to interventions to manage T2DM are confined to the few studies included in this review. Additionally, several interventional studies related behavioural interventions for managing T2DM were excluded only because the studies did not report means and respective dispersion values of outcomes at post intervention of the intervention and control groups. Nevertheless, these limitations had definitely encouraged to carry out more research to determine the best possible behavioural intervention regime in managing HbA1c levels for treating

T2DM more effectively and efficiently. From this analysis, it can be said that behavioural interventions do contribute towards effective management of T2DM. However, it should also be noted that, these findings might be changed or adjusted with addition of other new studies to the meta-analysis.

5. CONCLUSIONS

Behavioural interventions (coping skills and strategies) are reasonably effective in managing glycated hemoglobin (HbA1c) level of the T2DM individuals. These interventions are also functional in improving the sense of physical well-being in this population. Having said that, many more in depth researches are essential to figure out and establish the long-term benefits of behavioural interventions in managing the complications of T2DM.

6. ACKNOWLEDGEMENTS

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7. CONTRIBUTION OF AUTHORS

Conceived and designed the experiments:

FaS, SoS

Collected data and performed the experiments:

FaS, SrS, SoS, WMIWM

Contributed with materials/analysis tools:

FaS, SrS, SoS

Analysed the data: FaS, SrS, SoS

Wrote the paper: FaS, SrS, SoS

Checked and edited the format of the paper:

FaS, SrS, SoS

Final approval: FaS, SrS, SoS, WMIWM, MSHI

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APPENDIX

Characteristics of studies on behavioural interventions for type 2 Diabetes Mellitus included in review

Study	Population	Comparators used	Intervention	Duration	Results												
Whittemore et al (2004)	53 women (between 30 and 70 years)	Usual care/standard care	6-month nurse-coaching sessions	<p>Nurse-coaching sessions were provided every 2 weeks for 3 sessions, every month for 2 sessions, and lastly, after 3 months. A total of 6 nurse-coaching sessions were provided over 6 months, with 5 of the 6 sessions provided in the first 3 months.</p> <p>Two brief phone calls were provided between the fifth and sixth nurse coaching sessions.</p>	<table border="1"> <thead> <tr> <th colspan="4">Post Intervention</th> </tr> <tr> <th>Outcome measure</th><th>Control group</th><th>Intervention group</th><th>Results</th></tr> </thead> <tbody> <tr> <td>HbA1c (%)</td><td>7.5 ± 1.0</td><td>7.5 ± 1.0</td><td>No difference</td></tr> </tbody> </table>	Post Intervention				Outcome measure	Control group	Intervention group	Results	HbA1c (%)	7.5 ± 1.0	7.5 ± 1.0	No difference
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Outcome measure	Control group	Intervention group	Results														
HbA1c (%)	7.5 ± 1.0	7.5 ± 1.0	No difference														
Deakin et al (2006)	314 Adults (means age 61.5 years)	Usual care/standard care	The X-PERT program	This intervention program involved six weekly sessions, each lasting 2 hours.	<table border="1"> <thead> <tr> <th colspan="4">Post Intervention</th> </tr> <tr> <th>Outcome measure</th><th>Control group</th><th>Intervention group</th><th>Results</th></tr> </thead> <tbody> <tr> <td>HbA1c (%)</td><td>7.8 ± 1.6</td><td>7.1 ± 1.1</td><td>↓</td></tr> </tbody> </table>	Post Intervention				Outcome measure	Control group	Intervention group	Results	HbA1c (%)	7.8 ± 1.6	7.1 ± 1.1	↓
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Outcome measure	Control group	Intervention group	Results														
HbA1c (%)	7.8 ± 1.6	7.1 ± 1.1	↓														
Olivarius et al (2001)	970 Patients (aged ≥ 40 Years)	Usual care/standard care	Regular follow up and individualized goal setting	Regular follow up and individualized goal setting supported by prompting of doctors, clinical guidelines, feedback, and continuing medical education.	<table border="1"> <thead> <tr> <th colspan="4">Post Intervention</th> </tr> <tr> <th>Outcome measure</th><th>Control group</th><th>Intervention group</th><th>Results</th></tr> </thead> <tbody> <tr> <td>HbA1c (%)</td><td>9.0 ± 2.4</td><td>8.5 ± 1.8</td><td>↓</td></tr> </tbody> </table>	Post Intervention				Outcome measure	Control group	Intervention group	Results	HbA1c (%)	9.0 ± 2.4	8.5 ± 1.8	↓
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Outcome measure	Control group	Intervention group	Results														
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