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The effect of talk test-based aerobic exercise on pulmonary functions and quality of life among adults with type 2 diabetes mellitus: A randomized controlled trial

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Abstract

Introduction: Talk test is widely accepted and costless subjective tool for exercise intensity prescription. However, its utility in diabetes rehabilitation is unexplored. Therefore, the objective of present study was to evaluate the effectiveness of talk test based aerobic exercise on pulmonary function test (PFT) and quality of life (QOL) among adults with Type 2 diabetes mellitus (T2DM).

Material and methods: 90 patients were assigned to three groups: talk test group (TTG = 30), rating of perceived exertion group (RPEG = 30), and Control Group (CG = 30). 8-wks of supervised training was followed by 4-wks of unsupervised exercise at home for both the experimental groups. Forced Vital Capacity (FVC) and Forced Expiratory Volume at 1st second (FEV1) were measures of PFT. QOL was assessed through World Health Organization Quality of Life-brief Questionnaire (WHOQOL-BREF).

Results: PFT improvement in TTG & RPEG is superior to CG. However, there is no significant between group difference ($p > 0.05$). Further, the effect size in TTG was lesser than RPEG from baseline to 8-wk, 1.21 versus 1.46 and 1.42 versus 1.56 respectively for FVC and FEV1. However, it was more in TTG i.e. 1.26 and 1.08 in comparison to RPEG i.e. 0.51 and 0.57 respectively for FVC and FEV1 from 8-wk to 12-wk. The improvement in all the domains of QOL was significantly high in TTG & RPEG ($p < 0.01$) as compared to CG.

Conclusions: The PFT and QOL among adults with T2DM can be improved through the aerobic exercise based on talk test. Additionally, talk test based exercise is more effective than RPE based exercise during unsupervised sessions.

Keywords: quality of life, aerobic exercise, type 2 diabetes mellitus, pulmonary function test

Introduction

The incidence of diabetes mellitus (DM) has increased to such an extent that it has become a global epidemic [1]. The most common form worldwide is type 2 diabetes mellitus (T2DM). Similarly, the Indian Council of Medical Research (ICMR) notes that 90-95% cases of DM in Indian adults are T2DM [2]. T2DM is a chronic, non-communicable disease with a multisystem pathology. Chronic hyperglycemia caused by diabetes may lead to retinopathy, nephropathy and neuropathy [3]. Recent literature also suggests that the lung may also be a target organ for pulmonary complications; indeed, pulmonary complications of diabetes are so well explored that the term "diabetic lung" has been coined [4], and many studies have reported pulmonary function deterioration among T2DM patients [5−7].

The chronic hyperglycemia resulting from DM has both physical and psychological effects on the patient, and has a great impact on the quality of life (QOL) of a patient with diabetes: a restricted life style, need for long-term medication and fear of diabetes-induced multisystem complications are anxiety and reduced QOL [8]. The World Health Organization (WHO) defines QOL as "Individuals perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [9]. In turn, the relationship between QOL and DM is a reciprocal one, as poor perception of QOL may also affect the prognosis for DM [10]. Therefore, QOL is the most stipulated outcome following diabetes rehabilitation.

Exercise is an integral component of diabetes rehabilitation, along with diet and medication, various types of exercises such as aerobics, resistance training and yoga are recommended for patients with T2DM [11]. In such patients, it is recommended to prepare an individualized prescription of exercise based on the FITT principle i.e. frequency, intensity, type, and duration. Of these, the most crucial element is intensity, as this is required to gain the optimal benefit from any exercise. Aerobic exercises have also been demonstrated to have beneficial effects on pulmonary function and QOL among patients with T2DM [12−14].

However, previous trials have typically used objective measures to determine exercise intensity. This limits their utility in a real-world situation due to the sophistication, complexity and high price of objective tools. In contrast, subjective tools are inexpensive, easy to implement and understandable, and are realistic to use, even in home settings. The most commonly used subjective tool for determining exercise intensity is the rate of perceived exertion (RPE) [15], which provides a good indication of the metabolic response to functional training [16]. Moreover, its validity is well proved among patients with T2DM [17]. Another tool for estimating subjective exercise intensity is the talk test (TT) [18]; however, although it is gaining popularity, its utility in the diabetes rehabilitation remains unexplored.

Therefore, the present trial was planned to evaluate the effectiveness of TT-based aerobic exercise on pulmonary functions and QOL among adults with Type 2 diabetes.

Material and methods

The study was performed as a three-arm, double-blinded (accessor and trainer) randomized controlled trial reported as per CONSORT guidelines (2010). The procedure was in accordance with the Declaration of Helsinki (2013) and ICMR guidelines (2018). The research protocol was also approved by the institutional ethics committee (IEC) via letter no. PTY/2018/710A dated 31-10-2018. The trial has been registered in Clinical Trial Registry of INDIA (CTRI) with registration no. CTRI/2019/02/017531

Participants

The study included 90 T2DM patients, both male and female, with a duration of diabetes greater than one year and a Rapid Assessment of Physical activity (RAPA) [19] score below six. The age of the participants ranged from 40 to 64 years. The exclusion criteria were comprised of obesity (BMI $\geq$ 30 Kg/m^2), smoking, stage II hypertension, or the presence of any other chronic complication of diabetes or any other cardiorespiratory, musculoskeletal, vascular and neurological disorder that could affect the study outcome.

The subjects were conveniently selected from the outpatient department (OPD) of a primary care centre in north India from July 2019 to March 2021. Written informed consent was taken from each participant before the commencement of the study.

Stratified randomization was performed on the basis of two important prognostic factors, *viz.* sex [20] and glycaemic control [21]. Disproportionate stratified sampling was chosen for sex (60:40 ratio), as determined through the pilot trial [22] and a large survey study on the same population [23]. The randomization sequence for group allocation, based on the block size for each stratum, was generated by the Supervisor. These sequences were sealed in opaque envelops by the supervisor, and the first author followed the sequence in the suggested order. The study objective was blinded to trainer and outcome assessor (PFT technician).

Procedure

The participants were randomly assigned to three groups: these comprised one control group (CG; n = 30) and two experimental groups, comprising the talk test group (TTG; n = 30) and the perceived exertion group (RPEG; n = 30). The patients in the CG were instructed to walk for 45–50 minutes, including warm up and cool down, five days a week for 12 weeks. The patients in the experimental groups were enrolled for supervised walking on treadmill, at 1% gradient [24],

Tab. 1. Exercise protocol for the experimental groups

Time course	Frequency	Intensity	Time
Baseline to Week 4	5 times/week • Supervised: 3 times/week • Unsupervised: 2 times/week	For TTG: Comfortable level of talking For RPEG: 11–12*	45–50 min (including warm up and cool down)
Week 4 to Week 8		For TTG: At comfortable-difficult level of talking For RPEG: 13–14*	

TTG – Talk test group; RPEG – Rating of perceived exertion group; * on 6–20 scale.

for eight weeks (Table 1). After eight weeks of supervised intervention, the patients in experimental groups were instructed to walk at home at the approximately same intensity. A follow-up reading was also taken at week 12 for all the groups. All exercise sessions included a 10 minute warm up and five minute cool down.

Outcome measures

Each participant completed a RAPA questionnaire on their initial visit to the OPD. Recent HbA1c was obtained from the patient reports. The outcome measures for the study comprised pulmonary function test (PFT) and the quality of life (QOL). PFT was recorded by a Helios 401 Desktop spirometer (RMS, INDIA), whose reliability was assessed in a pilot trial [25]. The test was performed as per the quality standard of the American Thoracic Society (ATS) [26] and was recorded by a certified technician. Forced vital capacity (FVC) and forced expiratory volume at the first second (FEV_1) were used to evaluate pulmonary functions. Forced expiratory flow at 25-75% of the pulmonary volume (FEF 25–75%) and peak expiratory flow rate (PEFR) were also recorded from the PFT.

QOL was evaluated with the Hindi version of World Health Organization Quality of Life-brief Questionnaire (WHOQOL-BREF), which is found to be reliable among the Indian population [27]. It has good content validity, internal consistency (0.66 to 0.84), and test-retest reliability (0.66 to 0.87) [28]. The questionnaire consists of 26 items in four domains: physical health, psychological health, social relationships and the environment. it was completed by the patients themselves. The raw data from the completed questionnaire was transformed and scored using SPSS Syntax [9]. Both the outcome measures were recorded at baseline, after 8 weeks and at 12 weeks.

Statistical analysis

Data were analyzed using the SPSS 21 version. The normality of the data was checked using the Shapiro-Wilk test. Intention-to-treat (ITT) analysis was also performed, with the missing data due to drop out being imputed using multiple ITT analysis. Baseline comparisons between the groups were performed one using one-way ANOVA for continuous data and the Chi-square test for categorical data. As the data was normally distributed, pulmonary function was analyzed using parametric tests. Groups were compared with one-way ANOVA. Pair-wise comparison was performed with the paired t-test. The analysis of repeated measurements between time point and group was performed by repeated measures of ANOVA. The QOL was analyzed with the Wilcoxon signed ranks test, Kruskal-Wallis test, and Friedman test as the data was skewed. The significance level was set at $p \leq 0.05$. Categorical and continuous data were presented as n (%) and mean ± SD. The effect size was calculated with Cohen's d.

Results

A total of 272 patients were evaluated for eligibility. Following the exclusion and inclusion criteria, 90 patients were randomized into the three groups. The flow diagram of the study, in accordance with CONSORT guidelines, is given in Figure 1. The baseline demographics of the study population are given in Table 2. No significant differences were found between the groups at baseline ($p > 0.05$).

The between-group comparison of means found that the experimental groups (TT and RPE) demonstrated superior pulmonary functions, i.e. FVC and FEV_1, than the control group (CG). However, this difference proved to be insignificant based on one-way ANOVA for between-group comparison ($p > 0.05$). Furthermore, significant time effects were found for FVC (Wilkis' Lamda ($\wedge$) = 0.405 and 0.302, F = 20.608 and 32.31, $p < 0.01$ and < 0.01 and effect size (η^2) = 0.595 and 0.698) and FEV_1 ($\wedge$ = 0.324 and 0.267, F = 29.194 and 38.390, $p < 0.01$ and < 0.01, and η^2 = 0.676 and 0.733) for TTG and RPEG respectively.

The within-group comparison found a significant increase in FVC and FEV_1 for both the experimental groups

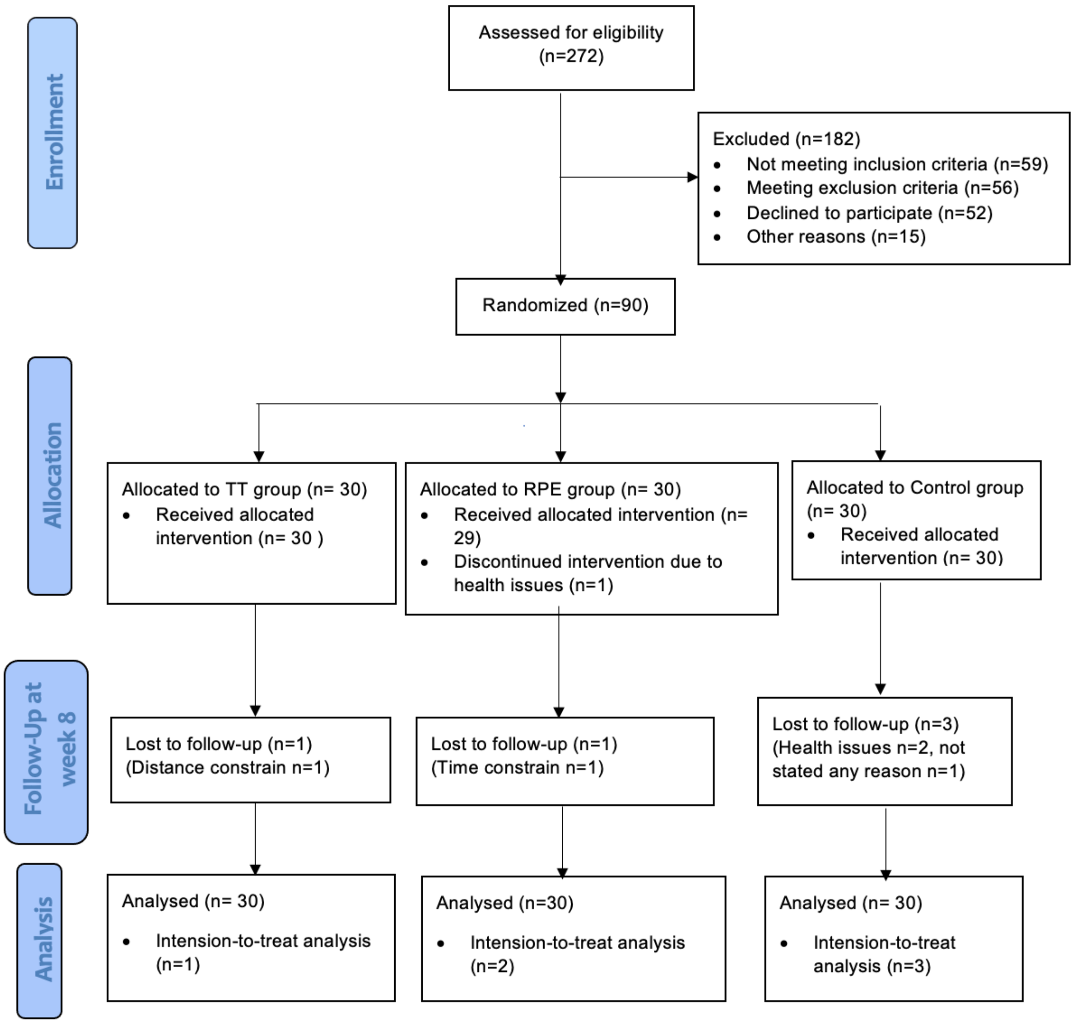

Fig. 1. Flow diagram of the study, as per CONSORT guidelines
TT – talk test; RPE – rating of perceived exertion.

Tab. 2. Baseline characteristics of the study participants of all the groups

Variables*	TTG (N = 30) Mean ± SD	RPEG (N = 30) Mean ± SD	CG (N = 30) Mean ± SD	p-value
Age (years)	51.17 ± 6.75	51.37 ± 6.38	49.53 ±7.37	0.55
Sex (Male/Female)	12/18	12/18	12/18	1.00
Body mass index (kg/m^2)	26.33 ± 3.15	26.42 ± 2.53	25.41 ± 3.19	0.35
Duration of diabetes (years)	5.17 ± 2.57	5.47 ± 2.67	5.07 ± 3.11	0.85
RAPA Score	3.5 ± 0.97	3.13 ± 0.90	3.57 ± 1.04	0.16
HbA1c (%)	7.4 ± 1.1	7.4 ± 1.1	7.5 ± 1.2	0.95
$FEF_{25–75}$ (l/s)	1.80± 0.38	1.81 ± 0.58	1.81 ± 0.40	0.99
PEFR (litre/second)	4.42 ± 1.29	4.24 ±1.06	4.25 ± 1.06	0.78
Predicted FVC (litre)	2.46 ± 0.47	2.58 ± 0.48	2.70 ± 0.59	0.22
Predicted FEV_1(litre)	1.91 ± 0.38	2.00 ± 0.41	2.11 ± 0.49	0.21

TTG – Talk test group; RPEG – Rating of perceived exertion group; CG – Control group; RAPA-Rapid assessment of physical activity; HbA1c – Glycated haemoglobin; FEF 25-75-Forced expiratory flow at 25–75% of the pulmonary volume; PEFR-Peak expiratory flow rate; FVC – Forced vital capacity; FEV_1-Forced expiratory volume in 1st second; *data is presented in mean ± SD.

($p < 0.01$) (Tab. 3, Tab. 4). Furthermore, from baseline to week 8, TTG demonstrated smaller effect sizes, i.e. 1.21 (FVC) versus 1.46 (FEV_1), compared to RPEG, i.e. 1.42 (FVC) versus 1.56 (FEV_1); however, from week 8 to week 12, TTG demonstrated higher effect sizes, i.e. 1.26 (FVC) and 1.08 (FEV_1), in comparison to RPEG, i.e. 0.51 (FVC) and 0.57 (FEV_1) (Tab. 3, Tab. 4). For the control group, a significant reduction in FVC was reported over time ($p < 0.01$) (Tab. 3); however, no significant reduction in FEV_1 was observed (Tab. 4).

The experimental groups (TTG and RPEG) showed a greater increase in QOL scores over time for all domains in comparison to the control group (CG), and this difference was significant ($p < 0.05$). For the within-group comparison, both TTG and RPEG demonstrated significant improvements in all domains of QOL from baseline to 12 weeks. However, from 8 to 12 weeks, all domains in the RPEG reported more negative ranks as shown in Table 5.

Tab. 3. Within-group comparison for Forced Vital Capacity

			Baseline to 8 weeks			8 to 12 weeks		
Group		FVC (liter) Mean ± SD	MD (95% CI)	d	p	MD (95% CI)	d	p
TTG	Baseline	2.19 ± 0.54	0.11 (0.08,0.15)**	1.21	0.00	0.04 (0.03, 0.06)**	1.26	0.00
	8 weeks	2.30 ± 0.50						
	12 weeks	2.34 ± 0.49						
RPEG	Baseline	2.09 ± 0.54	0.14 (0.11, 0.18)**	1.46	0.00	0.07, (0.02, 0.11)**	0.51	0.00
	8 weeks	2.23 ± 0.35						
	12 weeks	2.30 ± 0.32						
CG	Baseline	2.22 ± 0.38	–0.07 (–0.09,–0.06)**	1.69	0.00	–0.01 (0.02,0.01)**	0.55	0.00
	8 weeks	2.15 ± 0.52						
	12 weeks	2.14 ± 0.53						

TTG – Talk test group; RPEG – Rating of perceived exertion group; CG – Control group; MD – Mean difference; CI – confidence interval; d = effect size; FVC – Forced vital capacity; ** denotes $p < 0.01$.

Tab. 4. Within-group comparison for Forced Expiratory Volume at the first second

			Baseline to 8 weeks			8 to 12 weeks		
Group		FEV_1 (lit) Mean ± SD	MD (95% CI)	d	p	MD (95% CI)	d	p
TTG	Baseline	1.71 ± 0.40	0.12 (0.09, 0.15)**	1.42	0.00	0.03 (0.02, 0.05)**	1.08	0.00
	8 weeks	1.83 ± 0.37						
	12 weeks	1.87 ± 0.37						
RPEG	Baseline	1.65 ± 0.31	0.14 (0.11, 0.18)**	1.56	0.00	0.06 (0.02, 0.10)**	0.57	0.00
	8 weeks	1.79 ± 0.30						
	12 weeks	1.85 ± 0.27						
CG	Baseline	1.74 ± 0.40	–0.00 (–0.02, 0.00)	0.31	0.47	0.00 (–0.01,0.00)	0.18	0.62
	8 weeks	1.73 ± 0.41						
	12 weeks	1.73 ± 0.41						

TTG – Talk test group; RPEG – Rating of perceived exertion group; CG – Control group; MD – Mean difference; CI – confidence interval; d= effect size; FEV_1-Forced expiratory volume in 1^{st} second; ** denotes $p < 0.01$

Tab. 5. Within-group comparison of various domains of Quality of Life

Group		Baseline to 2 months NR, PR	Z	p	From 2 months to 3 months NR, PR	Z	p
TTG	Physical health	0.00, 15.50	4.79**	0.00	13, 15.07	1.46**	0.00
	Psychological	1.00, 15.50	4.69**	0.00	0.00, 9.50	3.74**	0.00
	Social relationship	10.50, 13.62	4.22**	0.00	6, 12.27	4.07**	0.00
	Environment	19.50, 14.31	4.19**	0.00	12, 9.19	2.7**	0.00
RPEG	Physical health	0.00, 15.50	4.78**	0.00	16.33, 11.50	2.71**	0.00
	Psychological	0.00, 15.50	4.78**	0.00	14.20, 9.63	3.49**	0.00
	Social relationship	0.00, 14.50	4.65**	0.00	13.35, 14.67	3.36**	0.00
	Environment	1.0, 13.50	4.55*	0.00	12.11, 11.08	0.57	0.57
CG	Physical health	7.75, 16.69	4.15**	0.00	8.83, 9.83	1.45	0.15
	Psychological	9.75, 11.77	1.31	0.19	7.50, 8.18	1.74	0.08
	Social relationship	6.25, 5.86	0.72	0.47	4.30, 3.23	1.27	0.20
	Environment	4.25, 3.90	0.94	0.35	1.75, 3.83	1.09	0.28

TTG-talk test group; RPE-rating of perceived exertion group; CG-control group; NR-Negative rank; PR-Positive rank; ** denotes $p < 0.01$; Z – Wilcoxon signed ranks test statistics.

Discussion

The results indicated that eight weeks of supervised aerobic exercise, evaluated with a subjective tool, *viz.* the TT or RPE, improved PFT and all the domains of QOL. Our findings are in line with those of the previous studies examining the effect of aerobic exercise on pulmonary function within this patient population [12,13]. However, these previous studies have favoured the use of objective tools of exercise intensity prescription [12,13].

The possible mechanism for the improvement of pulmonary function may be local or humoral as suggested by Ferdowsi et al [29]. Such observed improvements in pulmonary function could be attributed to increases in lung volume and elastic recoil, strengthening of respiratory muscles, and nor-epinephrine and epinephrine-mediated stimulation of the bronchial tree [29]. Additionally, the TTG was found to demonstrate smaller effect sizes for FVC and FEV_1 that the RPEG for the supervised session. This may be because the phonatory needs of speech production disturb the gas exchange, thus reducing the oxygen consumption, and increasing lactate production. This might have limited the ability to perform at the optimal prescribed intensity [30].

Furthermore, our findings indicate significant within-group improvement in QOL among the experimental groups, and significant between-group improvement compared to the controls (CG) after eight weeks of supervised aerobic exercise. Similarly, Bello et al found that eight weeks of supervised aerobic exercise (50–75% of maximum heart rate) on a bicycle ergometer significantly improved the QOL of the intervention group; however, no significant difference was found compared with the control group [31]. This could have been due to the low sample size (09 patients in each group) [32], or possibly the low frequency of sessions [31], i.e. three times/week, as a significant dose relationship has been observed between physical activity and QOL [33].

Furthermore, in the unsupervised sessions, the TTG demonstrated a greater effect size for improvement in FVC and FEV_1 compared to RPEG. Additionally, the RPEG showed deterioration in all domains of QOL, reflected in more negative ranks. One possible reason for this could be the difficulty associated with performing exercise without RPE scale in front during unsupervised home sessions, as reported by a patient in the RPEG.

In contrast, the TT is based upon speaking comfort. Speaking comfort can be easily evaluated by the patient through speaking in between exercises, and exercise intensity can be readjusted as required [18]. This approach therefore allows self-monitoring of exercise intensity, which is the mainstay of diabetes self-management education and support [33]. In addition, a recent scoping review found the coronavirus pandemic (COVID-19) to negatively impact self-management among these patients [34]; in such situations, exercise tools which promote self-management are the need of hour.

The greatest strength of the present study is that it demonstrates the effectiveness of subjective tools, *viz.* RPE and TT, based aerobic exercise in improving PFT and QOL among adults with T2DM. There is a strong need for such tools, which can be easily implemented in home settings, particularly in the midst of the COVID-19 pandemic. Patients with T2DM can easily perform safe and effective home exercise using these subjective tools. Our findings are further supported by the fact that the study controls for important confounding factors, i.e. by stratifying the sampling based on two important prognostic factors: Gender and glycaemic control. Finally, the TT approach can be integrated easily with mobile phone-based rehabilitation / telerehabilitation which has been found to be beneficial among these patients [35]; however, its value in telerehabilitation needs to be examined in future trials among these patients.

The present study has two potential limitations. Firstly, although the American Diabetes Association (ADA) advises that rehabilitation programs for patients with diabetes mellitus should include resistance exercise [11], the present study only used aerobic exercise training. Secondly, heart rate was not monitored during the exercise, as this was not possible in current settings.

Conclusion

Exercise evaluated by the talk test (TT) appears effective in improving pulmonary functions and quality of life among adults with type 2 diabetes. Additionally, while the TT may not be superior to RPE for supervised sessions, it may be more beneficial during unsupervised home sessions among this group.

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Conflict of interest
The authors declare no conflict of interest.

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