Section: Miscelleneous

Original Research Article

EFFECTIVENESS OF 'BEHAVIORAL CHANGE COMMUNICATION MODEL' IN PROMOTING PHYSICAL ACTIVITY AMONG FEMALES WITH TYPE 2 DIABETES MELLITUS: A RANDOMIZED CONTROLLED TRIAL

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Received *: 18/09/2025*
Received in revised form *: 07/11/2025*
Accepted *: 26/11/2025*

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DOI: 10.70034/ijmedph.2025.4.496

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2025; 15 (4); 2775-2783

ABSTRACT

Background: The marked discrepancy between predicted and actual prevalence of Type2 diabetes Mellitus (DM) with the actual cases rising earlier than expected, underscore the continuing relevance of tailored awareness and effective strategieslike promoting Physical Activity among female patients.
Materials and Methods: Design Randomized controlled trial. 86 females 30 - 65 years with type 2 DM attended Diabetic Clinic, South India from May to October 2006 including a one-week pilot study. Block randomized to intervention (43) and control (43) groups. Intervention- 'Behavioral change communication model, including 30 mints 'PA promotion video', last week recall and report of PA (IPAQ-international questionnaire) for 4 visits in 4 consecutive months and pamphlet. OUTCOME measures- Total and specific PA under four domains in Metabolic Equivalent Task Score, HbA1C, Total knowledge score and stage of change of behavior. Baseline measurements included ethnicity, PA, occupation and source of water.
Results: ANCOVA(SPSS) for total PA/day adjusted for basal difference tot (B=0.096; P=0.007) and ordinal Logistic Regression analysis for intervention group to be in action stage (estimate=3.961 CI [2.596 ,5.326]; P<0.001) are significant. Welch t test for household PA is marginally non-significant (t =1.97; p=0.053). Hb A1c (t test, P=0.8117) & 'knowledge score' (Mann-Whitney, P= 0.501.) are not significant.
Conclusion: Total PA and readiness for behavioural change significantly high in intervention group. Knowledge score and HbA1c level changes need longer period to be manifested. High adherence and expressed willingness to continue the programme are key strengths of the study.NCT:00690326
Keywords: Physical activity, DM type2, exercise adherence, glycaemic control.

INTRODUCTION

This study was done in 2015 motivated by the burden of type 2 diabetes, it's multi-organ dysfunctions and complexities in optimising diabetes care.[1] These challenges call for standard management protocols to be supplemented by additional interventions such as physical activity to achieve optimal glycaemic control. Epidemiological trends indicated a significant increase in prevalence, with global diabetic populations estimated 135 million in 1995 and projected to rise to 300 million by 2025.[2] his context highlighted the need for research into effective strategies tailored for specific population.
Alarming projection discrepancy: The projected number 300 million which was estimated to reach by 2025 had already skyrocketed to 537 million by 2021 drastically surpassing the predictions highlighting the rapidly escalating global diabetes epidemic.[3] The International Diabetes Federation (IDF) estimated that 537 million people worldwide had diabetes as of 2021, with the prevalence of diabetes mellitus among adults aged 20 to 79 years ranging from 6.1% to 11.1% in recent years. By 2045, this figure is

expected to increase to 783 million. Type 2 diabetes mellitus (T2DM) accounts for about 95% of these cases.pmc.ncbi.nlm.nih+2The overall prevalence of diabetes in India rose from roughly 7.1% in 2009 to 11.4% in 2023. With a projected 101 million diabetics in 2023 and 152 million expected by 2045, India has the second-highest number of diabetics worldwide. In 2018, the National NCD Monitoring Survey found that 9.3% of people had diabetes.[4]
Diabetes Mellitus type 2, Management, and the Role of Physical Activity.[5]
A central pathological feature of T2DM is insulin resistance, which renders insulin ineffective, thereby preventing glucose molecules from entering the cells. The most proximal behavioural factor contributing to insulin resistance is physical inactivity, which along with obesity, significantly drives the condition's pathogenesis.[6,7] Long-term diabetes exerts systemic effects, damaging large and small arteries in almost all vital organ systems, including the eyes, nerves, kidneys, and coronary arteries.[8] Premature atherosclerosis is linked to 75% of deaths among both Type 1 and Type 2 DM patients, with cardiovascular disease representing the most common cause of mortality
Physical activity (PA) is highly effective, low-cost, non-pharmacological intervention crucial for metabolic control.[9] The mechanism of PA involves reducing insulin resistance, thereby enhancing the efficacy of the available insulin. Exercise training improves glucose tolerance, burns calories, upregulates insulin receptors, and decreases free fatty acids. Specifically, PA increases the muscle's capacity for glucose disposal and transport.[10,11] The protective mechanisms of PA include the regulation of body weight, reduction of hypertension, improvement of dyslipidaemia, and enhancement of endothelial function.[12] Beyond metabolic control, other recognised benefits of PA include improved cardiorespiratory function, reduced symptoms of depression and anxiety, increased bone density, and a decreased risk of breast cancer in women.[13]
Guidelines by CDC, Centres for Disease Control and Prevention US recommend engaging in moderate intensity physical activity for a minimum of 30 minutes daily.[14] This level of activity generally corresponds to 3 to 6 METS (Metabolic Equivalent Task Scores) or the expenditure of 3.5 to 7 calories per minute, encompassing activities such as skipping, dancing, or brisk walking.
Physical Inactivity and Behavioural Change Interventions. Behavioural change models provide a framework for designing effective interventions.[15-17] Key determinants influencing PA include attitude, behavioural intention, social influence, self-efficacy expectations, knowledge of daily physical activity, and personal barriers.[18] The Transtheoretical Model (TTM), introduced by Prochaska and colleagues in 1982, proposes five sequential stages for examining behaviour change, the pre-contemplation, contemplation, preparation, action and maintenance.[19] By delivering stage-matched materials based on motivational readiness(appendix), cost-effective interventions can be designed to target individuals who are prepared to initiate change.[20,21]
As an aside, very recent estimation in south India revealed that females are found more affected by diabetes 86.26%) and those in Kerala are following sedentary lifestyle habits as evidenced by a regional study.[22,23] Wearable technology, smartphone sensor data, integration of GPS technology with Geographic Information System (GIS) data are anticipated to enhance physical activity surveillance systems.[24-26] Hopefully, this can enable and enhance the development of tailored interventions that address both individual needs and environmental contexts, as for example women with type 2 diabetes mellitus. It remains essential to concurrently investigate effective behavioural change communication strategies to promote context specific physical activity culture for tailored population.

MATERIALS AND METHODS

Design randomized controlled trial. 86 females 30 - 65 years with type 2 DM attended outpatient diabetic clinic at government tertiary care hospital, south India from May to October 2006 including a one-week pilot study. Block randomized with Random allocation application (RALLOC) to intervention (43) and control (43) groups.

Sample Size

$n=Z^{1-\alpha/2}[^2S^2] /d^2$

- S-pooled standard deviation from pilot study 18, α=5%
- d=Precision-10 (10% of mean)
- Desired CI-95%, two tailed
- no. in one arm=39
- Expecting 5% dropouts
- 39/ (1 - 0.05)2 =43

Intervention: 'Behavioural change communication model, including physical activity promotion video (appendixIII), pamphlet (ref AppendixI) and last week recall and report of physical activity using an interview schedule for 4 visits in 4 consecutive months. BCC administered to '15 members groups' each time explaining what is DM type 2, insulin resistance, role of PA to reduce insulin resistance and how to become physically active. It is explained how to include physical activity in routine life of a female with role models. Pamphlet explained the same given to control group too. reinforcement in subsequent 4 visits in following 4 months.
Adverse event reporting -collection approach was non-systematic - reported if any and enquired during interview schedule during preplanned visits

1. Physical injuries or pain related to increased activity (e.g., muscle strains, joint pain
2. Hypoglycemic episodes caused by increased physical activity like fainting
3. Cardiovascular symptoms like chest pain, excessive fatigue, or shortness of breath.

4. Any other unexpected health deterioration or complications triggered by the behavioural change program.

Outcome measures: Total and specific PA under four domains measured in minutes of Metabolic Equivalent Task Score using PA questionnaire and converted to total calories spent per day, HbA1C, Total knowledge score and stage of change of behaviour (appendix V&VI). In addition to these variables, baseline measurements included age, ethnicity, body weight, occupation and source of water.

Recruitment Sampling Method

- From Diabetic clinic OP on Fridays.
- out of around 80 patients attending OP, 40 are females.
- Recruited around 22 patients consecutively following consent, inclusion and exclusion criteria by two assistants using a Health screening (Appendix II) questionnaire

Inclusion Criteria: females with type2 Diabetes mellitus on 30-65yrs.

Exclusion Criteria: 2 patients from same family, those with complications nephropathy, H/O myocardial infarction, those who had been advised by doctor not to exert.

Pilot study done in 15 subjects to assess pooled variance for sample size calculation, the questionnaires and FGD (focus group discussions) among them. Expert opinion and review by a team of Diabetologists and department of clinical epidemiology.

Allocation to 2 groups according to the randomised allocation number.

Randomisation

- Randomised controlled trial, Block randomisation done by statistician using Random allocation software Ralloc, a statistical application for creating and managing randomization sequences in controlled trials.

Random Allocation Software (RAS) provide with complete control over every facet of randomization, such as block design, o Features: Both simple and blocked randomization settings are included in the app. There is no need for extra manual formatting

FLOWCHART

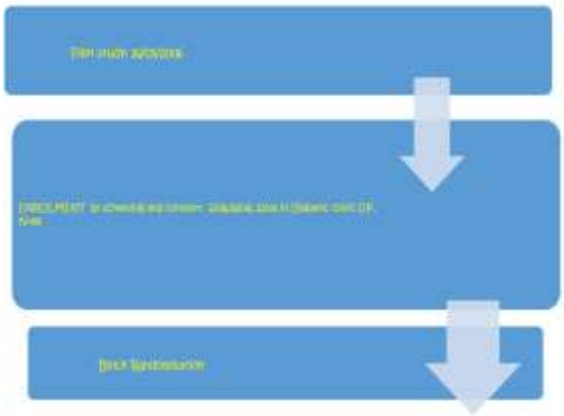
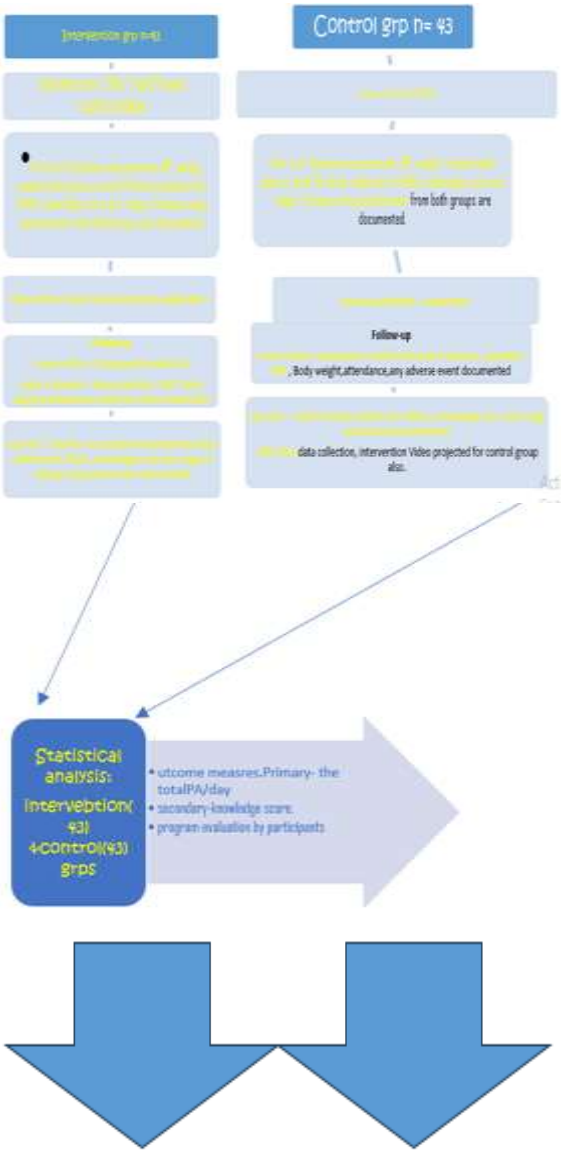


Figure 2



Timeline

- Ethical committee clearance got on 17/5/06 (appendix IX)
- Thesis protocol was presented at Dept. of medicine and Diabetology faculty on 19/5/06
- Pilot study 15 patients on 26/5/2006
- Patient screening &recruitment on 2/6,16/6,23/6,30/6, 7/7/2006.Informed about the program, collected address & telephone numbers. Follow up once in a month (4 times) measure physical activity and reinforcement done with video in each visit.

Tools

Collection procedure: By trained assistants using the interview Schedule for Physical activity promoting program among females with type II diabetic mellitus (Appendix VII)

The Section – I of the interview schedule collects Personal data, demographic data and Clinical Data relevant for this study.

Section – II of the interview schedule collects Knowledge of diabetes & physical activity Under following domains

Occupational, domestic, transportation and leisure time Physical activity

Section – III. The IPAQ (International Physical Activity) Questionnaire- long form recall & report over last one week.[27,28] It collects Moderate and heavy Physical activity frequency of the subject in minutes for past 1 week which is converted into energy expenditure using the formula. Energy expenditure (kcal per min) = 0.0175 kcal x MET score x minutes spent x Bodyweight (kg)

METS (Metabolic Equivalent Task Score) of specific activities are given by data compiled from 'compendium of Physical activities an update of Activity Codes and MET intensities.[29] Thus, a total activity score is calculated by adding 4 domains total PA for one day calculated by dividing number of days.[30,31]

-recall &report over a period of last one week.

PA calculated as Energy expenditure (kcal per min) =0.0175 kcal x METS (Metabolic Equivalent Task Score) x minutes spent x Body Weight in kilogram. METS of specific activities are given by data compiled from 'compendium of Physical activities 32 Total PA in calories/day calculated by dividing with number of days.

Secondary objectives were

1. Blood glucose change HbA1C (glycated haemoglobin concentration)
2. Knowledge of diabetes & physical activity
3. changes of stage of behaviour using questionnaire
4. To evaluate the program after the study by the participants
5. measured by Glycosylated Hb (HbA1c)
6. Change in knowledge score measured with a set of 7 questions before and after the study. (Arbitrary scoring given by the investigator. The knowledge score measured with a set of 7 questions (Score 1for each correct answer) regarding diabetes, insulin resistance and PA.

3.Assessment of stage of behavioural change by 'SOC' using questionnaire

Precontemplation - not thinking about change, Contemplation-thinking about change, preparation-doing some physical activity, action -doing enough physical activity and maintenance stage- making physical activity a habit.

Pilot study:

During the pilot study, the interview schedule questionnaires were administered by 2 interviewers in diabetic clinic for 15 random female patients. first interviewer asked the questions, the second interviewer also completed the same questionnaires in next visit. The completed questionnaires were compared using Kappa statistics for agreement regarding physical activity and knowledge score measurements. Agreement for total PA METs was Kappa 0.7867, Z 12.14, P<0.01 and administration time was 25 to 30 minutes. Piloting helped to give training for the assistants in diabetic clinic in different elements of research process, to estimate the variability in measured PA in METs to calculate sample size and to discard culturally irrelevant question which was not answered by all and to modify the question. Pooled standard deviation calculated after; PA was measured as average expenditure/day. To calculate the weekly physical activity (MET-mints /week), the number of minutes dedicated to each activity class was multiplied by the specific MET score for that activity. Average taken to get Total physical activity per day in calories.

Intervention group participants were invited by telephone and postal message.

- **Intervention-** Visual module projection on 7/7,8/7,14/7/2016
- Pamphlets for control grp 15/7,21/7 blood collected for HbA1c.
- 1st day projection arrangement done with the help of private arrangement, following 3 arrangements by Institute of Nova Kidney Foundation on recommendation from Dept. Of Nephrology, TVM medical college. Visits were conveniently fixed on Fridays- Diabetic clinic op. Followed up till3rd Friday of October.

During the last visit blood collected for HbA1c.

RESULTS

Table 1: Baseline Measure Description: Table 1_Basal measurements

BASAL MEASUREMENTS		
	Intervention group(43)	**Control group(43)**
Age (yrs) years		
<50	21	19
51-65	22	24
Mean(SD)	52.33(7.29)	51.63(7.73)
Body weight(kg)		
41-60	29	27
60<	14	16
Mean(SD)	58.94(7.33)	60.31(7.45)
Duration of Diabetes(yrs)		
<10	33	36
>10	10	7
Water source		
well	13	10
pipe	30	33

Exposure to media		
TV	39	40
Health magazines	4	3
Socio economic class		
lower	37	40
Upper lower	6	3
Un employed		
	40(93%)	37(86%)
Total PA/day(calories)		
Median(inter quartile range)	181.25(25.19)	187.0(32.60)
Log mean(SD)	5.185(0.094)	5.215(0.121)
HbA1C(gm%)		
Mean(SD)	6.40(0.85)	6.63(1.01)
SOC(stage of change)		
Pre contemplation	98%	97%
contemplation	2%	3%
Knowledge score(max 7)		
Mean(SD)	1.28(0.45)	1.07(0.26)

Age was calculated in years with 2 decimal places, then truncated to the nearest completed year for baseline reporting. 52.53(7.30);51.63(7.73)

Ethnicity-All participants belong to south India, Kerala

Bodyweight-

Intervention grp n=43; mean Weight (SD)58.94(7.33)

Control grp n=43;60.31(7.45)

Weights were rounded the nearest whole number to a precision of 0.5kg ≥500 gram to the higher and <500 gram to the lower whole number. Calories burnt is proportional to body weight for a specific physical activity.

Occupation

40/43 (93%) of the control group and 37/43 (86%) of the intervention group are not employed.

Understanding a woman's employment status allows for more effective physical activity programs. Programs can offer personalized strategies, provide context-specific interventions and deal with unique barriers. Those unemployed must include more physical activities related to household works.

Socio economic status. 37/43 of intervention and 40/43 of control group belong to upper lower class and the rest to lower class.[33,34]

Leisure time PA-None of the intervention and control groups used to participate in any recreational physical activity.

Source of water

Among the participants, 10 out of 43 (23.26%) and 13 out of 43 (30.23%) reported using wells as their water source. However, family members assisted in transporting the water to the home. The remaining participants had access to piped water. Understanding these different water sources is essential in planning and designing physical activity programs, as it highlights a substantial component of women's household physical activity. These observations indicate the physical inactivity among the participants.

The HbA1c

serves as the gold standard for monitoring long-term blood glucose level control35,36. Guide therapeutic decisions, and predicting a person's risk for serious diabetes-related health problems. Physical activity will reduce insulin resistance and maintain a good glycemic control. means and standard deviations for HBA1C Before **BCC**

Intervention group mean (SD) =6.4047(0.853) gm%

Control/comparison group 6.6349(1.0094)

Data analyzed with SPSS

Outcome data total physical activity in METs found skewed. Log transformation done for analysis.

Table 2: Total PA after intervention in calories/day

	Occupational PA		**House hold PA**		**Transportational PA**	
	Log mean(SD)	**Geometric mean(SD)**	**Log mean(SD)**	**Geometric mean(SD)**	**Log mean(SD)**	**Geometric mean(SD)**
Intervention grp(N=43)	0.71(1.62)	2.03(5.05)	4.08(1.20)	59.3(3.32)	4.29(0.81)	72.9(2.25)
Control grp(N=43)	1.50(2.19)	4.48(8.94)	3.42(1.84)	30.6(6.30)	3.84(1.64)	46.6(5.16)

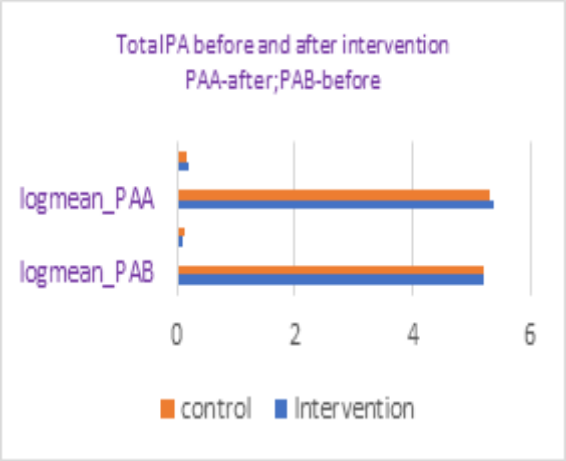


Figure 2: Total PA/day after intervention Period

1. The Welch's t-test for household PA t =1.970; p=0.0528; CI [-0.006,1.326]
Cohen's d = 0.425.
2.ANCOVA adjusted for baseline physical activity'. Levene's test sig 0.08; assumption of homogeneity is met. R square 0.305 explains 30.5% of variance. Effect of intervention group is B=0.096; P=0.007 after adjusting for total physical activity before intervention. So, belonging to intervention group is associated with higher adjusted mean log of METs after intervention. Partial eta squared for group(int/control) is 0.084 which is the effect size
3.t test for Hb A1c-t test after intervention period: After BCC, mean &SD 6.0465;0.6974
Control/comparison group, 6.0881;0.8984. t statistic= -0. 2388.P = 0.8117
CI [-0.3881,0.3047].
4) Mann-Whitney test for two independent samples - change in knowledge score.
U = 976.5, Z = 0.65, p = 0.50. (r =0.07).
5) PLUM-An ordinal Logistic Regression analysis examining the grouping variable(int/control), knowledge score, and exposure to media to outcome higher stage of change-contemplation and action.
Model Fitting Information -Chi-Square=58.792, P<0.001 indicating the predictors overall contribute significantly to predicting stages of behavior.
Goodness-of Fit=Pearson 6.129 significance=0.727 indicate the model fits the data well.
Grouping variable intervention is significant P<0. 001.estimate=3.961, CI [2.596 -5.326]
participants in intervention group have high odds of being in a higher stage of behavior. Nagelkerke R square=0.661 explain 66.1% of variance in ordinal outcome of change
of stage from pre to contemplation stage. Knowledge score and exposure to media have no significant effects P >0.05
SOC
97% of subjects of control group and 98% of intervention groups were at Pre-contemplation stage (stage-1). The stage in which individuals are unaware of problem and have no desire to change. Only 3% in control group and 2% of intervention groups were at contemplation stage (stage-2) the stage in which individuals are aware of a problem and have an intention to change the lifestyle by incorporating medium and moderate PA in their routine life. After the intervention, 43% of control and 90% of intervention groups were at action stage(stage-3) in which individuals started practicing those plans they have made during the preparation stage.
6) Post intervention participant evaluation: After the study period the audio visual module was introduced to the control group also and an evaluation of the BCC model was done using a Post test evaluation questionnaire (appendix VIII). All of them agreed that they enjoyed and accepted the programme and benefited by feeling self-motivated to change their sedentary life style and to incorporate more moderate intensity physical activities into their routine life.

DISCUSSION

Key themes evolved during focus group discussion were lack of awareness concerning the benefits of physical activity specific to DM, that moderate intensity household activities were as effective as structured daily walk or exercise programmes. They believed that daily walking and exercise were primarily relevant for individuals who had undergone heart operations (bypass and angioplasty).
Family members' lack of scientific understanding of diabetes mellitus, physical activity, and insulin resistance was specifically blamed for the prevalent sedentary lifestyle among women over 50 who received support from their families for routine PA-related activities like carrying water from the well.
The intervention was successful in increasing reported total physical activity per day and shifting participants into higher stages of behavioural change.[37,38] Even though specific components of PA lacked statistical significance, household PA showed a moderate practical importance reinforcing the positive functional impact of the intervention. The ANCOVA for total PA showed a statistically significant association between the intervention group and adjusted post-intervention in calories spent through physical activity per day. Furthermore, the intervention group showed had higher odds of moving into a more active stage of behaviour contemplation. However, effect of intervention was not yet reflected in statistical significance for clinical outcomes (HbA1c) and cognitive outcomes (knowledge score) during the 'four month' study period.
Independent samples t-test, the Welch's t-test for household PA failed to reject the null hypothesis. t =1.970; CI [-0.006,1.326]. P=0.0528 Not significant
But observed difference is confirmed to be of moderate practical importance (Cohen's d = 0.425), indicating that the intervention effect size is meaningful, regardless of the marginal statistical

outcome. 95% Confidence Interval for the difference in log means [-0.006, 1.326]).

Outcome data total physical activity in METs found skewed. Log transformation done for 'ANCOVA adjusted for baseline physical activity'. Levene's test sig 0.08; assumption of homogeneity is met. R square 0.305 explains 30.5% of variance. Effect of intervention group is B=0.096; P=0.007 after adjusting for total physical activity before intervention. So, belonging to intervention group is associated with higher adjusted mean log of METs after intervention. Partial eta squared for group(int/control) is 0.084 which is the effect size (TABLE1)

Comparison of total PA/day under different domains after intervention period between the intervention and control group. Intervention group has a higher geometric mean indicating greater average calorie expenditure in household PA (59.3, 72.9) than control group (30.6, 46.6) But variability is greater in control groups by a larger standard deviation (6.30,5.16) than intervention group (3.32,2.25), indicating more diverse household activity levels and a greater heterogeneity in transport-related activity among control group. Uniformity among intervention group can be related to the intervention BCC received by the group and communication among them.

1.97% control group and 98% the intervention groups were in pre contemplation stage, the phase where people don't want to change and aren't aware of the issue.

Following the intervention, 90% of the intervention groups and 43% of the control groups were in the action stage (stage 3), where they began putting their preparation-stage plans into practice.

PLUM-An ordinal Logistic Regression analysis examining the grouping variable(intervention/control), knowledge score, and exposure to media to outcome higher stage of change-contemplation and action.

Grouping variable has significant effect size (estimate=3.961, CI [2.596 -5.326]

participants in intervention group have high odds of being in a higher stage of behaviour. Nagelkerke R square=0.661 explain 66.1% of variance in ordinal outcome of change of stage from pre contemplation to action stage. knowledge score and exposure to media have no significant effects P >0.05.

4) Mann-Whitney test for two independent samples - change in knowledge score. No significant difference between two groups P 0.501.

"The Mann-Whitney U test comparing the intervention (n=43), and control (n=43) groups showed no statistically significant difference (U = 976.5, Z = 0.65, p = 0.50). The effect size was small (r=0.07). The with a 95% confidence interval from 0.0 to 1.0, indicating minimal difference in central tendency between groups."

HbA1c testing is the gold standard for monitoring long-term blood glucose control, guiding treatment decisions, and predicting risks of serious diabetes complications. Physical activity reduces insulin resistance and helps maintain good glycaemic control. Similarly, knowledge about diabetes, insulin resistance, and the role of physical activity—measured by a 7-question questionnaire—can positively influence attitudes and behaviours toward physical activity. Increased scientific understanding can shift individuals from pre-contemplation to action stages, making both HbA1c levels and physical activity knowledge important factors in promoting increased physical activity and improving diabetes outcomes. However, a longer study period more than 4 months is needed to confirm the effects of intervention as motivation and awareness on HbA1c level and change in knowledge score.

compliance

Patients demonstrated compliance to the programme, evidenced by attendance rates 100%. The results, combined with findings from the pilot study, suggest that most barriers encountered were related to the patients' medical conditions and internal factors such as self-efficacy and motivation, underscoring the importance of a behavioural change intervention featuring strategies acceptable to this specific population.

Strength& limitation

Knowledge score and HbA1c level changes need longer period to be manifested. Moreover, long term effect of 'BCC model' on bodyweight also to be included in future scope of study

High adherence and expressed willingness to continue the programme are key strengths of the study.

CONCLUSION

The study confirmed that women with diabetes are willing to adopt more active daily routines as guided by the BCC model. Motivation and reinforcement are proven effective strategies for promoting physical activity and developing responsibility for the self-management of Type2 Diabetes mellitus by the patients.

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