

1. Title

Effectiveness of 'Behavioural Change Communication Model' in Promoting Physical Activity Among Females with Type 2 Diabetes Mellitus: A Randomized Controlled Trial.

2. Introduction

Rationale of the Study: The global prevalence of Type 2 Diabetes Mellitus (T2DM) is rising rapidly, far surpassing previous predictions. A central pathological feature of T2DM is **insulin resistance**, which is significantly driven by **physical inactivity**. While physical activity (PA) is a low-cost, effective non-pharmacological intervention, it remains underutilised, particularly among females in certain social contexts. In South India, females are highly affected by diabetes and often follow sedentary lifestyles. This study addresses the need for tailored behavioural change strategies to promote a context-specific physical activity culture.

3. Review of Literature

- **Global Burden:** The number of people with diabetes was projected to reach 300 million by 2025 but already hit 537 million by 2021.
- **Role of PA:** Exercise improves glucose tolerance, upregulates insulin receptors, and reduces insulin resistance.
- **Behavioural Change:** The **Transtheoretical Model (TTM)** provides a framework for behaviour change through five stages: pre-contemplation, contemplation, preparation, action, and maintenance.
- **Interventions:** Stage-matched materials and motivational readiness assessments can create cost-effective interventions for individuals prepared to initiate change.

4. Materials & Methods (Methodology)

- **Research Question:** Will a "behavioural change communication model" implemented in a Diabetic Clinic OP among females with Type 2 DM be effective in making them more physically active?.
- **Aim:** To evaluate the effectiveness of a BCC model in promoting physical activity among female T2DM patients.
- **Objectives:**
 - **Primary:** To measure the increase in physical activity in Metabolic Equivalent Task (MET) scores using a PA questionnaire.
 - **Secondary:** To assess changes in **HbA1C** levels, knowledge of diabetes and PA, and the stage of behaviour change.
- **Hypothesis:** A standardized BCC model will improve physical activity, knowledge, and the stage of behaviour change in the intervention group compared to a control group receiving only pamphlets.
- **Study Design:** Randomized controlled trial (RCT).
- **Setting:** Diabetic Clinic outpatient department at a government tertiary care hospital in South India.
- **Sampling:**
 - **Sample Size:** 86 females (43 in the intervention group, 43 in the control group).
 - **Inclusion Criteria:** Females with Type 2 DM aged 30–65 years.

- **Exclusion Criteria:** Patients with complications (nephropathy, H/O myocardial infarction), those advised against exertion, and multiple patients from the same family.
- **Sampling Procedure:** Consecutive recruitment followed by **block randomization** using RALLOC software.
- **Methods:**
 - **Data Collection:** Trained assistants use an interview schedule to collect demographic, clinical, and PA data (IPAQ-long form).
 - **Intervention:** The **BCC model** includes a 30-minute PA promotion video, pamphlets, and recall/report of PA over four monthly visits.
 - **Outcome Measurement:** Total and specific PA under four domains (occupational, domestic, transportation, leisure) measured in MET scores and converted to calories/day.

5. Plan of Analysis

- **Statistical Software:** SPSS.
- **Analysis Methods:**
- Data distribution will be analysed. If normal distribution, parametric methods will be used. If skewed distribution, normalisation of data and non-parametric methods will be considered.
 - Baseline physical activity difference will be adjusted for comparing the control and intervention groups.
- **Sample Size Calculation:** Based on a 95% CI and a pooled standard deviation (18) from a pilot study of 15 subjects

- **sample size calculation**

Estimating the difference between two means
SD from pilot study-18

$$n = z^* - a / 2(2sp^*) / d^*$$

- 2-tailed
- Precision-10)
- Desired CI-95%
- no. in one arm=39
- Expecting 5% drop outs
- $39 / (1 - .05)^2 = 43$

Sampling Method

Consecutive sampling from Diabetic clinic OP for 5 consecutive Fridays based on screening questionnaire with inclusion and exclusion criteria

6. Policy Implications

The study highlights that motivation and reinforcement are effective strategies for fostering self-management responsibilities in T2DM patients. Implementing such behavioural models in clinical settings can help bridge the gap between patient awareness and actual lifestyle changes.

7. References

References should be formatted in **Vancouver style**.

8. Annexures

- **Instrument of Measurement:** International Physical Activity Questionnaire (IPAQ) short form
- **Knowledge & SOC Questionnaires:** 7-question knowledge set and Stage of Change (SOC) assessment.
- **Ethical Clearance:** Obtained on 17/05/2006.
- **Consent Forms:** Provided in English and local languages.