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## Research Article

# Exploring The Efficacy Of Auricular Acupuncture In Managing Type 2 Diabetes Mellitus Utilizing Freestyle Libre Pro Continuous Glucose Monitoring As The Primary Outcome Measure: A Pilot Randomized Controlled Trial Protocol

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## ABSTRACT

Diabetes mellitus, particularly Type 2 diabetes, poses a significant global health challenge with increasing prevalence rates. Despite available treatments, achieving optimal glycemic control remains a challenge. Acupuncture, an ancient therapy, has shown promise in managing diabetes. However, its efficacy on specific auricular acupuncture points in Type 2 diabetes remains underexplored. This study aims to investigate the efficacy of auricular acupuncture targeting the pancreas point, endocrine point, and point zero in improving glycemic control in individuals with Type 2 Diabetes Mellitus, utilizing Freestyle Libre Pro continuous glucose monitoring. A Pilot Randomized Controlled Trial design will be employed. Twenty participants aged 30-60 years with confirmed Type 2 diabetes will be recruited and randomized into two groups: a study group receiving auricular acupuncture and a control group receiving sham acupuncture. The primary outcome will be changes in mean glucose levels assessed via

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Freestyle Libre Pro continuous glucose monitoring. Secondary outcomes include changes in insulin sensitivity measured by Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) scores. Data analysis will be conducted using appropriate statistical tests to determine the efficacy of auricular acupuncture on glycaemic control and insulin sensitivity in individuals with Type 2 Diabetes Mellitus. This study aims to contribute to the growing body of evidence on the efficacy of acupuncture in managing Type 2 diabetes, particularly focusing on auricular acupuncture points. The findings may have implications for improving diabetes care and warrant further investigation in larger clinical trials.

## **INTRODUCTION**

The World Health Organization (WHO) approximates that more than 400 million individuals worldwide are affected by diabetes, with projections indicating a rise to 592 million by the year 2035(1). Diabetes, a chronic metabolic disorder characterized by elevated blood glucose levels, poses significant risks to multiple organ systems, including the heart, blood vessels, eyes, kidneys, and nerves. Type 2 diabetes, typically occurring in adults, arises when the body develops insulin resistance or fails to produce sufficient insulin. Over the past three decades, the prevalence of type 2 diabetes has surged worldwide across diverse socioeconomic settings. Type 1 diabetes, previously referred to as juvenile or insulin-dependent diabetes, involves the pancreas producing minimal or no insulin autonomously. For individuals managing diabetes, access to affordable treatment, notably insulin, is indispensable for their well-being. A globally endorsed objective aims to halt the escalation of diabetes and obesity by the year 2025(1,2). Type 2 diabetes mellitus represents a significant global health challenge, with an estimated prevalence of 366 million in 2011, a figure expected to surge by 51% to reach 552 million by 2030. India mirrors this global trajectory, with a prevalence of 60 million in 2011, projected to escalate by 63% to reach a total of 97.8 million by the year 2030(1,3). This poses a significant threat to public health.

Inadequately controlled diabetes can result in severe and potentially fatal complications affecting the heart, liver, stomach, kidneys, muscles, as well as vascular and peripheral nerves. According to the Global Report on Diabetes, diabetic complications may include heart attacks, strokes, blindness, renal failure, and lower limb amputations. However, diabetes can be effectively managed through a range of therapeutic interventions(1,4). Acupuncture, an ancient form of alternative medicine with a history spanning over 2500 years, is widely practiced worldwide. It involves the insertion of needles at specific points on the body, known as acupoints, along meridians or energy pathways. Stimulation of these acupoints is believed to produce therapeutic effects that target specific areas or functions of the body(5). More than 2,000 years ago, the ancient Chinese medical text, *Yellow Emperor's Classics of Internal Medicine*, first documented the significance of the ear in relation to the human body. It highlighted the ear's connection to various internal organs and emphasized that all meridians converge at the ear. Recognizing the importance of standardizing acupoint locations, the Chinese Association of Acupuncture and Moxibustion was entrusted by the World Health Organization (WHO) with the task of establishing consistent acupoint locations. This standardization aimed to facilitate uniformity and coherence in the study and exchange of ideas within the field of acupuncture(6). Stimulation of the ear acupoint MA-IC 3 Endocrine is facilitated by the anterior vagus rami auricularis, a branch of the vagus nerve responsible for innervating internal organs. Through acupuncture-mediated stimulation of this nerve, there's a potential activation of pancreatic beta cells, leading to insulin secretion. Acupuncture may also modulate the sympathetic or parasympathetic nervous systems. Stimulation of parasympathetic nerves via cholinergic fibers prompts the release of acetylcholine, which



stimulates insulin secretion and influences pancreatic beta cell receptors. Additionally, this process triggers the secretion of proteins involved in insulin signaling, such as insulin-like growth factor. These mechanisms could underlie the observed increase in insulin action induced by acupuncture, potentially enhancing insulin sensitivity while reducing insulin resistance(7). Previous research has predominantly focused on evaluating the efficacy of acupuncture in achieving glycemic control, employing various acupoints. For instance, a study conducted by R. Kumar et al. in 2017 observed a notable decrease in Random Blood Glucose levels within 30 minutes following acupuncture needling at CV-12 acupoint in patients with Type 2 Diabetes Mellitus (T2DM)(3). According to national diabetes guidelines, the current standard of care for assessing glycemic control in hospital settings and adjusting insulin therapy relies on bedside point-of-care capillary glucose testing (POC). This method involves glucose testing before meals and at bedtime. However, POC testing has limitations, as it does not offer a complete 24-hour glycemic profile assessment and may miss asymptomatic or nocturnal hypoglycemia. Consequently, the utilization of Continuous Glucose Monitoring (CGM) has seen a significant expansion in recent years. CGM provides the advantage of continuously measuring interstitial glucose levels every 5-15 minutes, offering a comprehensive 24-hour glycemic profile assessment and enabling better detection of nocturnal and asymptomatic hypoglycemia. Additionally, CGM allows for pattern recognition after treatment. Large-scale studies utilizing CGM have demonstrated its efficacy in facilitating and enhancing diabetes care in ambulatory patients treated with insulin, regardless of diabetes type(8). In a study conducted by Sergio Vencio et al. in 2021, the impact of acupuncture on glycemic control in individuals with Type 2 Diabetes was investigated

using Continuous Glucose Monitoring (CGM). The findings revealed a decrease in mean glucose levels and enhancements in overall glycemic control throughout the 14-day monitoring period among participants receiving acupuncture treatment(9). As of now, the therapeutic effects of auricular acupuncture on blood glucose levels in individuals with Type 2 Diabetes Mellitus have not been investigated on acupoints like Pancreas point, Endocrine point, and Point Zero. Therefore, this study represents a pioneering effort in investigating the time latency for such effects. The study will utilize the FreeStyle Libre Pro system developed by Abbott Diabetes Care to monitor blood glucose levels. This system is a flash glucose monitoring system that provides a comprehensive record of an individual's glucose levels, trends, and patterns over up to 14 days. Similar to continuous glucose monitoring, flash glucose monitoring relies on measuring glucose concentrations in the interstitial fluid rather than directly in the blood(10). As a result, this study has the potential to be groundbreaking in the field of acupuncture research.

#### **AIM AND OBJECTIVES:**

##### **Aim:**

To Explore the Efficacy of Auricular Acupuncture Points Pancreas, Endocrine, and Point Zero in Managing Type 2 Diabetes Mellitus Patients.

##### **Objectives:**

Primary Objective: To investigate the efficacy of auricular acupuncture targeting the pancreas point, endocrine point, and point zero in improving glycaemic control, as measured by changes in mean glucose levels assessed via Freestyle Libre Pro continuous glucose monitoring, in individuals with Type 2 Diabetes Mellitus. To investigate the change in mean glucose levels, as assessed by Freestyle Libre Pro continuous glucose monitoring, following auricular acupuncture targeting the pancreas point, endocrine point, and point zero, stratified by age groups (e.g., < 50



years old, 50-65 years old, >65 years old), in individuals diagnosed with Type 2 Diabetes Mellitus.

### **Secondary Objectives:**

To evaluate the effect of auricular acupuncture targeting the pancreas point, endocrine point, and point zero on insulin sensitivity, as measured by changes in Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) scores(11), in individuals with Type 2 Diabetes Mellitus.

### **Participating Units:**

#### **1. International Institute of Yoga and Naturopathy Medical Sciences, Chengalpattu (Outpatient Department):**

- This unit serves as the primary site for patient recruitment, intervention administration, and data collection. Located in Chengalpattu, it offers outpatient services specializing in yoga, naturopathy, acupuncture, and energy medicine.
- The Outpatient Department (OPD) of the International Institute of Yoga and Naturopathy Medical Sciences is responsible for identifying eligible participants, explaining the study protocol, obtaining informed consent, and conducting acupuncture interventions.
- Additionally, this unit will manage the follow-up visits, monitor participants' progress, and oversee data collection procedures throughout the study period.
- The OPD ensures adherence to the study protocol, ethical standards, and safety measures outlined by the Institutional Ethics Committee (IEC) and regulatory authorities.

### **Laboratories:**

- Although the study primarily focuses on clinical interventions and outcome assessments rather than laboratory analyses, certain biochemical parameters such as fasting plasma glucose levels may be

measured to confirm eligibility criteria or as secondary outcome measures.

- Laboratory facilities within the International Institute of Yoga and Naturopathy Medical Sciences or affiliated institutions may be utilized for any necessary laboratory analyses.
- The laboratories ensure accurate and timely processing of biological samples, adhering to standardized protocols and quality assurance measures.

### **Data Management Center:**

- The Data Management Center is responsible for overseeing data collection, storage, and analysis throughout the study.
- It may be located within the International Institute of Yoga and Naturopathy Medical Sciences or in a separate facility equipped with appropriate infrastructure and personnel.
- The Data Management Center ensures the confidentiality, integrity, and security of all study-related data, adhering to Good Clinical Practice (GCP) guidelines and regulatory requirements.
- Data management activities include data entry, cleaning, coding, validation, and statistical analysis.

### **Coordinating Centre:**

- The Coordinating Center serves as the central administrative hub responsible for coordinating various aspects of the study, including protocol development, regulatory submissions, participant recruitment, training of study personnel, and monitoring study progress.
- It may be housed within the International Institute of Yoga and Naturopathy Medical Sciences or operate as a separate entity closely collaborating with the study team.
- The Coordinating Center facilitates communication among investigators, study



personnel, regulatory authorities, and other stakeholders involved in the research.

- It plays a pivotal role in ensuring the smooth implementation of the study protocol, addressing any issues or concerns, and maintaining overall study integrity and compliance.

**Study Design:**

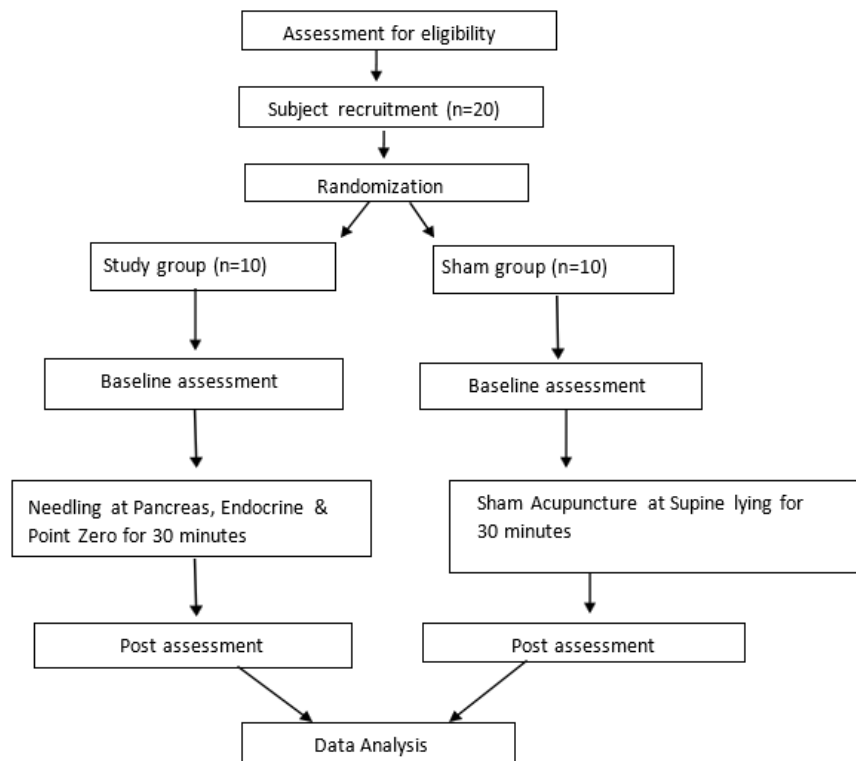
- The experimental design of the study is a Pilot Randomized Controlled Trial (RCT).
- Participants will be randomly assigned to either a study group or a control group.
- The study is single-blind, where participants are blinded to the intervention group they are assigned to. However, due to the nature of the intervention, blinding of the practitioners administering the acupuncture may not be feasible.

- Allocation concealment will be ensured using the Sequentially Numbered Opaque Sealed Envelope (SNOSE) technique to minimize selection bias.

**Study Population General Description:**

- The study population comprises individuals aged 30-60 years.
- Participants have a confirmed diagnosis of Type 2 Diabetes Mellitus (T2DM) with an HbA1c level of  $\geq 6.5\%$ .
- They have been on diabetes medication for the past 3 months.
- Participants have not undergone acupuncture treatment in the past month. Individuals willing to provide informed consent are eligible for inclusion in the study.

**Figure-1: Trial profile:**



**Sample Size Determination and Power Analyses:**

- The sample size for the study is determined to be n=20, with 10 participants allocated to each group (study group and control group).

- The sample size determination is based on the pilot nature of the study, aiming to explore the feasibility and potential efficacy of auricular acupuncture in managing T2DM.
- Power analyses may not be conducted for a pilot study due to the exploratory nature of the research and the absence of predetermined effect sizes.

### **Study Outcomes/Endpoints:**

#### **Primary Outcome:**

- Changes in mean glucose levels assessed via Freestyle Libre Pro continuous glucose monitoring.

#### **Secondary Outcomes:**

- Changes in insulin sensitivity measured by Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) scores.
- Continuous blood glucose levels will be measured using the Freestyle Libre Pro system
- The study aims to investigate the efficacy of auricular acupuncture targeting specific points in improving glycemic control and insulin sensitivity in individuals with T2DM.

### **Study Procedures**

#### **A. Subject Selection Procedures:**

- i. Sampling Plan including Inclusion/Exclusion Criteria:

#### **Inclusion Criteria:**

1. Age group 30-60 years.
2. Confirmed diagnosis of Type 2 Diabetes Mellitus (T2DM) with an HbA1c level  $\geq$  6.5%.
3. On diabetes medication for the past 3 months.
4. No prior acupuncture treatment in the past month.
5. Willingness to provide informed consent.

#### **Exclusion Criteria:**

1. Presence of open wounds, burns, or scalds in specific areas targeted for acupuncture.
2. Consumption of alcohol or psychotropic medication during the study period.
3. Diabetic complications.
4. Psychiatric illnesses other than mild depression.
5. Pregnancy or breastfeeding.
6. Current participation in other clinical studies.
7. Needle phobia.

#### **Recruitment Procedures:**

- Recruitment will primarily occur at the International Institute of Yoga and Naturopathy Medical Sciences, Chengalpattu (Outpatient Department), which serves as the primary study site.
- Consent will be obtained at the Outpatient Department of the International Institute of Yoga and Naturopathy Medical Sciences during the initial screening visit.
- Consent will be obtained before any study-related procedures are performed.
- Trained study personnel, including physicians or research assistants, will obtain consent from potential participants.
- Potential participants will be provided with brochures or information sheets detailing the purpose, procedures, potential risks, and benefits of the study.

#### **Screening Procedures:**

- Screening procedures will involve assessing potential participants for eligibility based on the inclusion and exclusion criteria outlined in the study protocol.
- This may include reviewing medical records, obtaining medical history, performing physical examinations, and conducting laboratory tests (e.g., HbA1c levels, fasting plasma glucose).
- Additionally, participants may undergo assessments to ensure they meet the age



criteria and have not undergone acupuncture treatment in the past month.

- The screening process may require one or multiple visits depending on the availability of required tests and assessments.
- The length of each screening visit will vary based on the complexity of procedures and participant factors but is generally expected to be relatively short, typically ranging from 30 minutes to an hour.

#### **Withdrawal criteria:**

Participants are free to withdraw from the study at any point in time, for any reason, with or without prior intimation to investigators or with or without prior permission from investigators.

#### **Randomization and Blinding:**

Participants will be randomly divided (1:1 ratio) into either a study group or a control group using simple random methods with computerized randomization. A simple randomization procedure will be performed for 20 subjects with a 1:1 ratio to get a sample size of (n=10) in each group. Allocation concealment will be done using the SNOSE (Sequentially Numbered Opaque Sealed Envelope) technique. The participants will be blinded to the study and control group intervention.

#### **Study Intervention:**

The study intervention involves two arms: the study group receiving auricular acupuncture and the control group receiving sham acupuncture.

##### **1. Study Group Intervention:**

- Participants allocated to the study group will undergo auricular acupuncture targeting specific points, including the pancreas point, endocrine point, and point zero.
- The acupuncture sessions will be conducted in a supine lying or sitting position for 30 minutes daily for a total of 14 days.
- Needling will be performed by trained acupuncture practitioners using sterile,

disposable needles of appropriate gauge and length

- The acupuncture points will be located and needled according to established guidelines and standards of practice in acupuncture therapy.
- Participants will receive a standardized acupuncture protocol, and the number of needles, depth of insertion, and duration of needling will be consistent across sessions.

##### **2. Control Group Intervention:**

- Participants allocated to the control group will receive sham acupuncture.
- Sham acupuncture involves the application of tape or adhesive material to simulate the placement of acupuncture needles without actual needling.
- Similar to the study group, participants in the control group will be positioned in a supine lying or sitting position for 30 minutes daily for 14 days.
- While participants in the control group will experience the sensation of tape application, they will not receive acupuncture needling.
- The sham acupuncture intervention is designed to control for non-specific effects such as placebo response or attention from the practitioner.
- Both study groups will be observed without any additional interventions during the 14-day period. Participants in both groups will be instructed to maintain their usual diabetes medication regimen and lifestyle practices throughout the study period unless otherwise advised by their healthcare provider.
- The intervention sessions will be conducted at the International Institute of Yoga and Naturopathy Medical Sciences, Chengalpattu, under the supervision of trained healthcare professionals. Any adverse events or discomfort experienced during the

intervention will be monitored and managed appropriately.

**Figure: 2 – Intervention Point and Its Location**



### Study Assessments and Activities:

#### 1. Primary Assessment:

- The primary outcome measure is changes in mean glucose levels assessed via Freestyle Libre Pro continuous glucose monitoring.
- Continuous glucose monitoring will provide a comprehensive 24-hour glycemic profile, enabling the evaluation of glycemic control throughout the study period.
- Glucose levels will be monitored every 5-15 minutes using the Freestyle Libre Pro system, providing real-time data on interstitial glucose levels.

#### 2. Secondary Assessments:

- Changes in insulin sensitivity will be measured using the Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) scores.
- HOMA-IR scores will be calculated based on fasting plasma glucose and insulin levels obtained at baseline and the end of the intervention period.
- Continuous blood glucose levels will be measured using the Freestyle Libre Pro system to complement the primary outcome assessment.

#### 3. Study Activities:

- Baseline Assessment: Before intervention initiation, participants will undergo baseline assessments including a medical history review, physical examination, measurement

of HbA1c levels, fasting plasma glucose, and insulin levels.

- Intervention Period: Participants will receive the allocated intervention (auricular acupuncture or sham acupuncture) daily for 30 minutes over 14 days.
- Outcome Assessments: Glucose levels will be monitored continuously using the Freestyle Libre Pro system throughout the intervention period. HOMA-IR scores will be calculated based on fasting plasma glucose and insulin levels obtained at baseline and post-intervention.
- Follow-up Assessment: At the end of the intervention period, participants will undergo follow-up assessments including measurements of HbA1c levels, fasting plasma glucose, and insulin levels to evaluate changes in glycemic control and insulin sensitivity.
- Adverse Event Monitoring: Participants will be monitored for any adverse events or discomfort experienced during the intervention period. Adverse events will be recorded, assessed for severity, and managed appropriately.
- Data Collection and Management: Study data, including glucose monitoring data, HOMA-IR scores, and adverse event reports, will be collected, recorded, and securely stored. Data management procedures will ensure data



integrity, confidentiality, and compliance with regulatory requirements.

- Statistical Analysis: Data analysis will be conducted using appropriate statistical methods to evaluate the efficacy of auricular acupuncture in managing Type 2 Diabetes Mellitus based on the study outcomes.

### **Safety Monitoring Plan:**

#### **1. Adverse Event Reporting:**

- All adverse events (AEs) occurring during the study will be documented, regardless of severity or suspected relationship to the study intervention.
- Adverse events will be recorded using standardized adverse event reporting forms.
- Participants will be encouraged to report any adverse events experienced during or after the intervention period.
- Healthcare professionals administering the intervention will also monitor participants for any signs of discomfort or adverse reactions during acupuncture sessions.
- Adverse events will be assessed for severity, causality, and expectedness.

#### **2. Monitoring and Management of Adverse Events:**

- Adverse events will be monitored throughout the study period, from the start of the intervention until the completion of follow-up assessments.
- Study personnel will promptly assess and manage adverse events as appropriate, ensuring participant safety and well-being.
- Mild adverse events may require reassurance and symptomatic treatment, while more severe events may necessitate medical intervention or discontinuation of the study intervention.
- Serious adverse events (SAEs) will be reported to the Institutional Ethical

Committee (IEC) and regulatory authorities as per regulatory requirements.

- Study investigators will be responsible for investigating the causes of adverse events, implementing corrective actions, and ensuring appropriate follow-up care for affected participants.

#### **3. Ethical Considerations:**

- The safety monitoring plan will adhere to ethical principles and regulatory requirements governing the conduct of clinical research.
- Participant safety and well-being will be paramount throughout the study, and all necessary measures will be taken to minimize risks and ensure ethical conduct.
- Informed consent procedures will include detailed information about potential risks associated with the study intervention, as well as procedures for reporting adverse events and accessing medical care.

#### **DATA ANALYSIS:**

Data analysis will be done using appropriate statistical tests using JASP software.

#### **DISCUSSION**

The proposed pilot randomized controlled trial aims to investigate the efficacy of auricular acupuncture in managing Type 2 Diabetes Mellitus (T2DM) using the Freestyle Libre Pro continuous glucose monitoring system as the primary outcome measure. This study addresses a significant gap in current diabetes management strategies by exploring a complementary and alternative treatment modality. T2DM is a chronic metabolic disorder that poses severe health risks, including cardiovascular diseases, renal failure, and neuropathy. Conventional treatments, primarily involving pharmacological interventions and lifestyle modifications, often fall short in achieving optimal glycemic control. Auricular acupuncture, an ancient therapeutic practice, has shown promise in regulating various physiological functions, including glucose metabolism, by



stimulating specific points on the ear. This study is pioneering in its use of continuous glucose monitoring to provide a comprehensive assessment of the glycemic effects of auricular acupuncture, potentially offering a novel adjunctive treatment for T2DM. One of the primary strengths of this study is the use of the Freestyle Libre Pro continuous glucose monitoring system. This system allows for the continuous measurement of interstitial glucose levels, providing a detailed 24-hour glycemic profile that surpasses the limitations of traditional point-of-care testing. Continuous glucose monitoring is particularly advantageous in detecting asymptomatic and nocturnal hypoglycemia, which are often missed by standard glucose monitoring methods. Another strength is the rigorous design of the study, including randomization and blinding, which minimizes bias and enhances the validity of the findings. The use of a sham acupuncture control group ensures that any observed effects can be attributed to the specific intervention rather than placebo effects or other confounding factors. The potential mechanisms through which auricular acupuncture may exert its effects on glycemic control are intriguing and warrant further exploration. Stimulation of the pancreas, endocrine, and Point Zero acupoints may activate pancreatic beta cells, enhance insulin secretion, and improve insulin sensitivity. Additionally, modulation of the autonomic nervous system, particularly the parasympathetic pathway, could play a role in regulating glucose metabolism. These mechanisms suggest a multifaceted approach by which auricular acupuncture may benefit individuals with T2DM. Despite its strengths, this study has several limitations. As a pilot study with a small sample size, the findings may not be generalizable to the broader T2DM population. Future studies with larger sample sizes and longer follow-up periods are necessary to confirm the findings and assess

the long-term effects of auricular acupuncture on glycemic control. Moreover, while the study aims to provide preliminary data on the efficacy of specific auricular acupuncture points, further research is needed to explore the optimal frequency, duration, and combination of acupoints for diabetes management. Investigating the effects of auricular acupuncture in combination with other complementary therapies or conventional treatments could also provide valuable insights.

## **CONCLUSION**

This study has the potential to contribute significantly to the field of diabetes management by providing preliminary evidence on the efficacy of auricular acupuncture in improving glycemic control in individuals with T2DM. The innovative use of continuous glucose monitoring enhances the robustness of the findings, offering a comprehensive assessment of glycemic patterns. If successful, auricular acupuncture could be integrated into diabetes care as a complementary approach, improving outcomes for individuals struggling with this chronic condition. Further research is warranted to build on these findings and explore the full potential of acupuncture in diabetes management.

## **CONFLICT OF INTEREST STATEMENT.**

The authors declare no conflict of interest regarding the publication of this research protocol. No funding was received from any commercial or financial entities that could influence the study's design, execution, or reporting. All authors have independently contributed to the development and implementation of the research protocol. The primary aim of this study is to explore the efficacy of auricular acupuncture in managing Type 2 Diabetes Mellitus, with no external influences or biases from commercial interests.

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