4. SCOPE AND PLAN OF THE WORK

4.1 Need of the Study

- In spite of numerous strategies that have been developed in the past few years in health care to improve diabetes care, the control and management of type 2 diabetes is still a challenge to the health care professionals.
- Diabetes treatment strategies should be individualized to match the need of every patient. However a general guideline or algorithm based on fasting blood glucose levels will essentially be needed.
- Diabetes management requires a multidisciplinary approach, where both nonpharmacological treatment and pharmacological treatment options are equally important as one another. Diabetes self management education (DSME) is the cornerstone in the treatment of diabetes. The mainstay of DSME is medical nutrition therapy (MNT), also known as diet, which includes physical activity or exercise as well. In the given study setup the influence of DSME through pharmaceutical care need to be studied and identified.
- There is a high prevalence of diabetes and hypertension in the rural areas of Nilgiris district.\(^{54}\)
- The *Madhumega chooranam* capsule (MMC) (Ingredients: Each 160 mg capsule contains: *Phyllanthus amarus* 20 mg, *Embilical officianalis* 50 mg, *Murraya koengi* 20 mg, *Picrorhiza kurroa* 50 mg, *Curcuma longa* 8.3 mg, *Trigonellafoenum graceum* 6.6mg) and *Nilavembu kudineer chooranam* (NKC) (Ingredients: each 100 g contains: *Andropraghis paniculata* 11.1g, *Vetiveria zizanoides* 11.1g, *Coleus ambonicus* 11.1g, *Santalum album* 11.1g, *Vetiveria zizanoides* 11.1g, *Coleus ambonicus* 11.1g, *Santalum album* 11.1g,
Tricosanthes cucumerina 11.1g, Cyperus rotundus 11.1g, Zingiber officinale 11.1g, Piper nigrum 11.1g, Mollugo cerviana 11.2 g) are the siddha formulations that are available at Siddha unit which are used for treating Type 2 Diabetes Mellitus at Government Hospitals in Tamilnadu, India.

➢ There are no reports available for the pharmacodynamic effects of Madhumega Choornam Capsule and Nilavembu Kudineer Chooranam when given alone and along with any of the following oral Anti diabetic agents viz. Glibenclamide, Metformin and Glimepiride.

➢ The guidelines for the Management of Type 2 diabetes given by ICMR, strongly recommend the research and careful evaluation of such indigenous system and the possibility of drug – herb interaction.55

➢ Similarly the American Diabetes Association (ADA) currently does not have any specific guidelines for the use of Complementary and Alternative Medicine (CAM) in patients with diabetes but has acknowledged its use in lieu of patients’ interest. Publications by the ADA do suggest a healthcare professional’s role in promoting the safe use of CAM therapies and helping guide patients on supplement selection based on safety.
4.2 Scope:

The report from this study will provide the valuable information in generation of newer treatment strategies for the management of type 2 diabetes mellitus by development of a new algorithm which utilizes the Siddha agents along with existing oral anti diabetic drugs. There is a considerable increase in diabetes prevalence and there is a substantial need for anti diabetic products. With the currently available limited treatment options in Government hospitals in Tamilnadu, India it is essential to use the interdisciplinary approach where the madhumegha chooranam and nilavembu kudineer chooranam can be used in addition to metformin/ glibenclamide/ glimepiride. This strategy may be beneficial due to any one or more of the following measures such as the replacement of allopathic drug, reduced dose requirement, lesser side effects or increased effectiveness.
4.3 Plan of the Work

From preliminary studies → Formulating the Research Question → Aims & Objectives

Literature Review
- Using Primary, Secondary and Tertiary Resources

Structuring the Study
- Scope and Plan of work
- Methodology
- Study Protocol
- Data Collection Forms

Ethical Committee Approval
- Protocol submission to Institutional Review Board
- Protocol revision (if any)
- Study Approval

Study Initiation
- Informed Consent process
- Subject Recruitment

Statistical analysis of data

Results
- Thesis writing
- Presentation
- Publication

Data Collection

Evaluation of antidiabetic activity of MMC & NKC

Gender wise Exercise Barrier Assessment

Assessment of Community Pharmacist’s contribution towards T2DM management