2. AIM AND OBJECTIVES
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Type 2 diabetes mellitus (T2DM) is a worldwide epidemic. It is associated with a high risk of microvascular and macrovascular complications leading to an equally high risk of premature death. Moreover, the quality of life of T2DM patients also gets deteriorated due to its chronic nature, related complications and life-long treatment.

Despite the availability of many antidiabetic agents and pharmacotheapies targeting cardiovascular risk factors, the morbidity, mortality and economic consequences of T2DM are still a great burden to patients, society, healthcare systems and the economy. Based on the current understanding of the pathophysiology of T2DM, multiple pharmacological and non-pharmacological interventions have been developed. But the existing treatments have limitations either because of their side effects, particularly weight gain and hypoglycaemia or contraindications that limit their use. Furthermore, none of the current therapies have a significant impact on disease progression. There is a need, therefore, for newer approaches that may have additional or better impact in patients with T2DM.

The use of complementary and alternative medicines (CAM) for the treatment of diabetes is common and increasing worldwide. Major reasons behind the diabetes patients turning to complementary therapies are symptomatic relief, control disease progression and to reduce the side effects associated with antidiabetic agents. Vitamins and mineral supplements are commonly used for primary or secondary disease prevention, but information about the efficacy and safety of herbs, vitamins or other dietary supplements for diabetes management is conflicting. Moreover, studies on the simultaneous use of herbal medicines with the conventional therapy are limited. Herbal medicines are readily available in the market in the different dose and dosage forms.
Aim and Objectives

It was, therefore, proposed to design and investigate health outcome measures and vascular risk factors in patients with T2DM receiving resveratrol (250 mg) and vitamin C supplementation (500 mg).

The major objectives of the present study are;

- to evaluate the clinical efficacy and glycaemic control of resveratrol (250 mg) and vitamin C (500 mg) in patients with T2DM patients,
- to evaluate the effect of resveratrol and vitamin C on vascular risk factors in patients with T2DM,
- To evaluate vascular risk factors in T2DM patients for identifying subjects susceptible for cardiovascular complications.
- To assess the health outcome measures in T2DM patients like,
  a) Health Related Quality of Life (HRQoL) using Audit of Diabetes Dependent Quality of Life (ADDQoL),
  b) Patient satisfaction with diabetes treatment modalities by using Diabetes Treatment Satisfaction Questionnaire (DTSQ) and
  c) Economic outcome measures of vitamin C and resveratrol supplementation along with the treatment in diabetes mellitus.
- To understand patient Knowledge, Attitude and Practice (KAP) and the pattern of adherence on medication in T2DM patients.

Plan of Work

The present project was proposed to be carried under following steps. The year wise plan is given in Table 2.

Step 1: Literature review

Step 2: Selection of site and study design.

Step 3: Designing standard data documentation forms.
Aim and Objectives

**Step 4:** Protocol approval by Institutional Ethical committee.

**Step 5:** Selection of subjects based on the inclusion and exclusion criteria.

**Step 6:** Obtaining consent from the patients.

**Step 7:** Enrolling patients to study and randomly allocating them into test and control group.

**Step 8:** Baseline evaluation.

**Step 9:** Study follow up evaluations.

**Step 10:** Statistical analysis and interpretation of data.

**Step 11:** Publication of results.

**Table 2: Year wise plan of work**

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