

## CLINICAL GUIDELINE FOR AYURVEDIC PRACTITIONERS TO MANAGE TYPE 2 DIABETES

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South Asia has one of the world's largest type 2 diabetes mellitus (T2DM) epidemics, a disorder with significant health and socioeconomic consequences.<sup>1</sup> In India and Nepal, it is one of the major health conditions for which individuals commonly consult Ayurvedic practitioners and use their medicines.<sup>2,3</sup> However, strong concerns remain about the suboptimal T2DM management of many patients by Ayurvedic practitioners.<sup>4,5</sup> A good quality T2DM clinical guideline, grounded on the best available scientific evidence, may address the existing problems, discourage the use of medicines of no, minimal or questionable value and encourage the use of effective and safe medicines.<sup>6</sup> The clinical guideline may close the gap between what they do to manage T2DM and what the scientific evidence supports.<sup>6</sup> We, therefore, secured highly competitive international funding from the UK's Department of Health and Social Care; Foreign, Commonwealth and Development Office; Medical Research Council; and Wellcome Trust Joint Global Health Trials for working on this topic. The main project partners are the University of Nottingham in the UK and the Nepal Health Research Council, the national apex body for health research in Nepal. Other project investigators are based at other world-class institutions, such as the London School of Hygiene and Tropical Medicine, University College London, University of Birmingham, All India Institute of Medical Sciences, Sree Chitra Tirunal Institute for Medical Sciences and

Technology (in India) and Ministry of Health and Population (in Nepal).

No T2DM clinical guideline is available in Nepal for Ayurvedic practitioners, but several such clinical guidelines are available in India to assist Western medicine and Ayurvedic practitioners, and therefore, a systematic review was conducted to evaluate and synthesise the content and quality of these clinical guidelines.<sup>7</sup> Several databases and sources were searched from inception, to identify clinical guidelines for managing adults with T2DM in India. No language restrictions were applied. The screening of titles and abstracts and full texts, data extraction and quality assessment were conducted by two independent reviewers. Any disagreements were resolved through discussion or by involving a third reviewer. A data extraction tool from our previous study was adapted to extract the content of the included clinical guidelines, and the Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool was used to assess the quality of the included clinical guidelines.<sup>8,9</sup> A narrative synthesis was conducted. Of 3,350 records identified, five clinical guidelines were included in this systematic review three focused on Ayurveda and two focused on Western medicine. Only Western medicine clinical guidelines contain comprehensive recommendations for managing T2DM, but only one of these is of high quality and can be recommended for managing T2DM by Western medicine practitioners in India. Clinical guidelines, especially for Ayurvedic practitioners, should be developed and updated using the standard clinical guideline manuals and quality appraisal tools.

Many Ayurvedic medicines have the potential to manage T2DM, and therefore, the objective of the second

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systematic review was to evaluate and synthesise evidence on the effectiveness and safety of Ayurvedic medicines for managing T2DM.<sup>10</sup> The JBI systematic review methodology was followed.<sup>11</sup> Published and unpublished randomised controlled trials (RCTs) assessing the effectiveness and safety of Ayurvedic medicines for managing T2DM in adults were included. RCTs were eligible if evaluated any classical or proprietary Ayurvedic medicine (e.g., containing plant- or mineral-origin ingredients—single or in combination) in any form (e.g., capsules, tablets, decoction, powder) with no intervention, placebo, non-pharmaceutical intervention (e.g., yoga) or pharmaceutical intervention (i.e., Western oral antidiabetic drug or head-to-head comparison with another Ayurvedic medicine). A comprehensive search of sources (including 18 electronic databases) from inception was made. No language restrictions were applied. The screening of titles and abstracts and full texts, data extraction, and quality assessment were conducted by two independent reviewers. Any disagreements were resolved through discussion or by involving a third reviewer. Data synthesis was conducted using narrative synthesis and random effects meta-analyses, where appropriate. Out of 32,519 records identified from the searches, 219 articles were included in this systematic review representing 199 RCTs (21,191 participants) of 98 Ayurvedic medicines. Overall, the methodology was not adequately reported in the included studies, resulting in poorer methodological quality scoring. We conducted meta-analyses on 33 Ayurvedic medicines (including 32 single herbs). Unfortunately, we could not include 65 Ayurvedic medicines in any meta-analysis, administered either as a single medicine or in combination with other Ayurvedic medicines, due to being evaluated in a single study. Glycated haemoglobin (HbA1c) was reduced using *Aegle marmelos* (L.) Corrêa (mean difference (MD) -1.6%; 95% confidence interval (CI) -3 to -0.3), *Boswellia serrata* Roxb. (-0.5; -0.7 to -0.4), *Gynostemma pentaphyllum* (Thunb.) Makino (-1; -1.5 to -0.6), *Momordica charantia* L. (-0.3; -0.4 to -0.1), *Nigella sativa* L. (-0.4; -0.6 to -0.1), *Plantago ovata* Forssk. (-0.9; -1.4 to -0.3), *Tinospora cordifolia* (Willd.) Hook.f. and Thomson (-0.5; -0.6 to -0.5), *Trigonella foenum-graecum* L. (-0.6; -0.9 to -0.4) and *Urtica dioica* L. (-1.3; -2.4 to -0.2) compared to control. Similarly, fasting blood glucose (FBG) was reduced by 4–56 mg/dL for a range of Ayurvedic medicines. Very few studies assessed health-related quality of life (HRQoL). Adverse events were not reported in many studies, and if reported, these were mostly none to mild and predominately related to the gastrointestinal tract. In conclusion, the current evidence

suggests the benefit of a range of Ayurvedic medicines in improving glycaemic control in T2DM patients. Given the limitations of the available evidence and to strengthen the evidence base, high-quality RCTs should be conducted and reported.

As reported in the first systematic review, a good quality T2DM clinical guideline for Ayurvedic practitioners, grounded on the best available scientific evidence, is not available, and therefore, the third study aimed to systematically develop a clinical guideline for Ayurvedic practitioners to manage T2DM in adults.<sup>12</sup> The development work was guided by the UK's National Institute for Health and Care Excellence (NICE) manual for developing guidelines, the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach and AGREE II tool.<sup>9,13,14</sup> The findings of the above-mentioned effectiveness systematic review (along with the Summary of Findings table prepared using the GRADE approach for assessing the certainty of the findings) were used,<sup>10</sup> and the Evidence-to-Decision framework was developed using the GRADE approach, focusing on glycaemic control and adverse events. Subsequently, based on the Evidence-to-Decision framework, a Guideline Development Group made recommendations on Ayurvedic medicines' effectiveness and safety in T2DM. The Guideline Development Group had 17 international members, consisting of Ayurvedic practitioners, Western medicine practitioners (including diabetologists), pharmacognosists and experts in medicinal plants and phytochemistry, systematic review methodologists, medical statisticians, epidemiologists, sociologists and people with T2DM. These recommendations formed the basis of the clinical guideline, and additional generic content and recommendations were adapted from the T2DM Clinical Knowledge Summaries of the Clarity Informatics (UK).<sup>15</sup> This approach was taken because the basic principle of T2DM management is the same in Western medicine and Ayurveda i.e., a combination of a healthy lifestyle and medicinal products. The feedback given by the Guideline Development Group on the draft version was used to amend and finalise the clinical guideline for managing T2DM in adults by Ayurvedic practitioners. The clinical guideline focuses on how Ayurvedic practitioners can provide appropriate care, education and support to people with T2DM (and their carers and family). The clinical guideline provides information on T2DM, such as its definition, risk factors, prevalence, prognosis and complications; how it should be diagnosed and managed through lifestyle changes like diet and physical activity and Ayurvedic medicines; how

the acute and chronic complications of T2DM should be detected and managed (including referral to specialists) and advice on topics like driving, work and fasting including during religious/socio-cultural festivals.

The research question to be addressed by a definitive cluster RCT is whether the introduction of a clinical guideline can improve the management of T2DM by Ayurvedic practitioners as compared to usual Ayurvedic management (i.e., without any clinical guideline). In preparation for this future work, we have conducted a feasibility cluster RCT in Nepal to determine the feasibility of undertaking the definitive cluster trial.<sup>16</sup> This is a two-arm, feasibility cluster RCT with a blinded outcome assessment and a qualitative evaluation. The study is conducted in 14 public and private Ayurveda centres in and outside the Kathmandu Valley in Nepal (1:1 intervention:control). Eligible participants are new T2DM adult patients (i.e., treatment naïve) – HbA1c should be 6.5% or above but less than 9%. We have recruited 121 participants (at least 60/group) and followed them up for six months. Important parameters, needed to design the definitive trial, are being estimated, such as the standard deviation of the outcome measure (i.e., HbA1c at 6-month follow-up), intraclass correlation coefficient, cluster size, recruitment, the time needed to recruit participants, follow-up and adherence to the recommended Ayurvedic medicine. Semi-structured qualitative interviews are being conducted with around 20 to 30 participants and all the participating Ayurvedic practitioners to explore their experiences and perspectives of taking part in the study and of the intervention and a sample of eligible people declining to participate in the study to explore the reasons behind nonparticipation. If the feasibility is promising (such as recruitment, follow-up and adherence to the recommended Ayurvedic medicine), then the parameters estimated will be used to design the definitive cluster trial. Decisions over whether to modify the protocol will mainly be informed by the qualitative data.

If the T2DM clinical guideline for Ayurvedic practitioners is found to be effective, people with T2DM will benefit from improved health outcomes, such as better blood glucose control and lower T2DM complications. The related future clinical, personal and economic burden on people with T2DM, their carers and family, the health system and the economy will be reduced. People with T2DM will be cared for in line with the best available scientific evidence and in the same manner, regardless of where or by which Ayurvedic practitioner they are treated. It is anticipated that the clinical guideline may close the

gap between what Ayurvedic practitioners do to manage T2DM and what the scientific evidence supports. It may also deter the usage of Ayurvedic medicines with no, minimal or questionable value, thus promoting the usage of effective and safe Ayurvedic medicines. While this clinical guideline is developed for Ayurvedic practitioners on the Indian subcontinent, it will also be relevant in countries with South Asian ethnic minorities who often rely heavily on Ayurvedic treatments.<sup>17,18</sup>

The project fits well with the 2022 World Evidence-Based Healthcare Day theme “Partnerships for Purpose” as the overarching purpose of this North–South–South equitable research partnership is to improve the management of T2DM by Ayurvedic practitioners.<sup>19</sup> This cross-country project is a collaboration between experts with complementary strengths: methodological expertise in intervention development and evaluation and experience working in large clinical networks. The project has brought together Western medicine and Ayurveda experts. There is mutual academic benefit and capacity-building by cross-sharing of expertise and experience within the team. The project has the potential to improve scientific links between the UK, India and Nepal (and more broadly through wider collaborative links and networking). □

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