



University of
Nottingham

Centre for Public Health and Epidemiology

Diabetes Management by Ayurvedic Practitioners in Nepal: A Feasibility Cluster Randomized Trial Comparing Clinical Guideline to Usual Practice and an Associated Qualitative Study

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CLINICAL GUIDELINE TO MANAGE DIABETES BY AYURVEDIC PRACTITIONERS: NORTH-SOUTH PARTNERSHIP



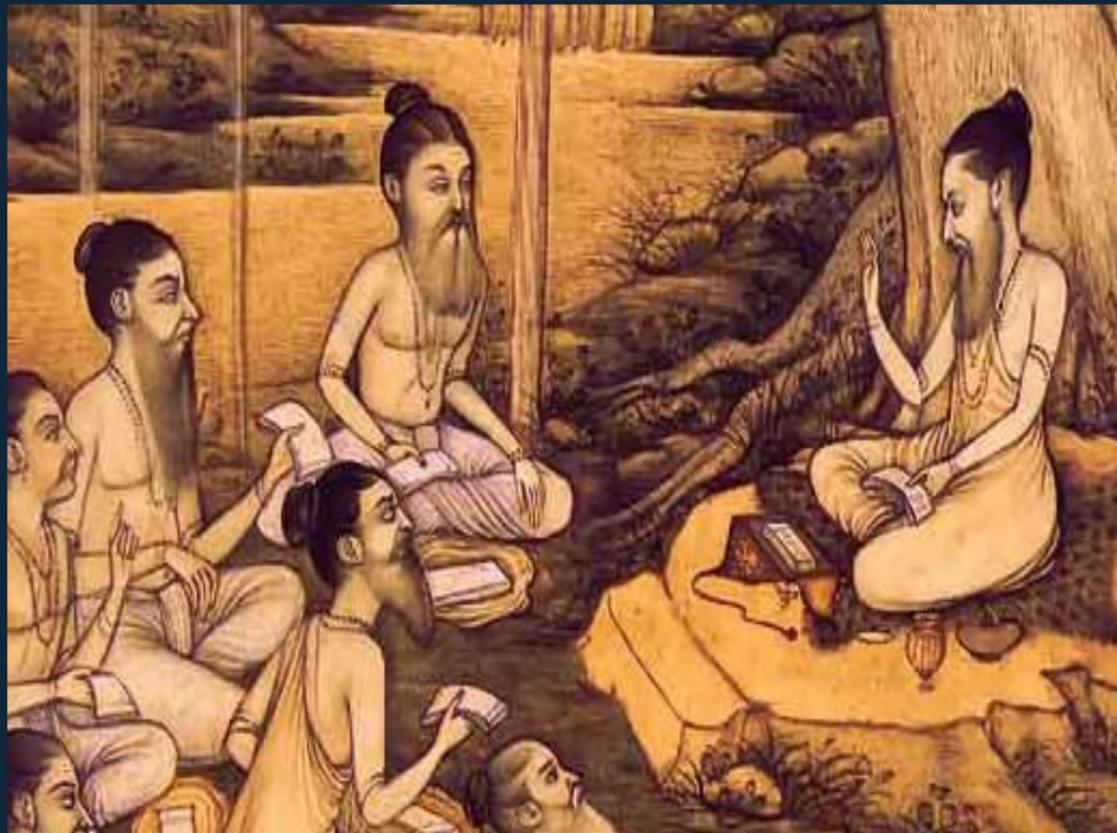
Government of Nepal
Department of Ayurveda and Alternative Medicine



LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE



Ayurveda in Ancient Times



Diabetes Management in Nepal

High prevalence of T2DM in the Nepalese population.

Prevalence

Many people seek care through Ayurveda, a popular traditional system.

Ayurveda

Concerns about suboptimal care and variability in practice among Ayurvedic practitioners persist.

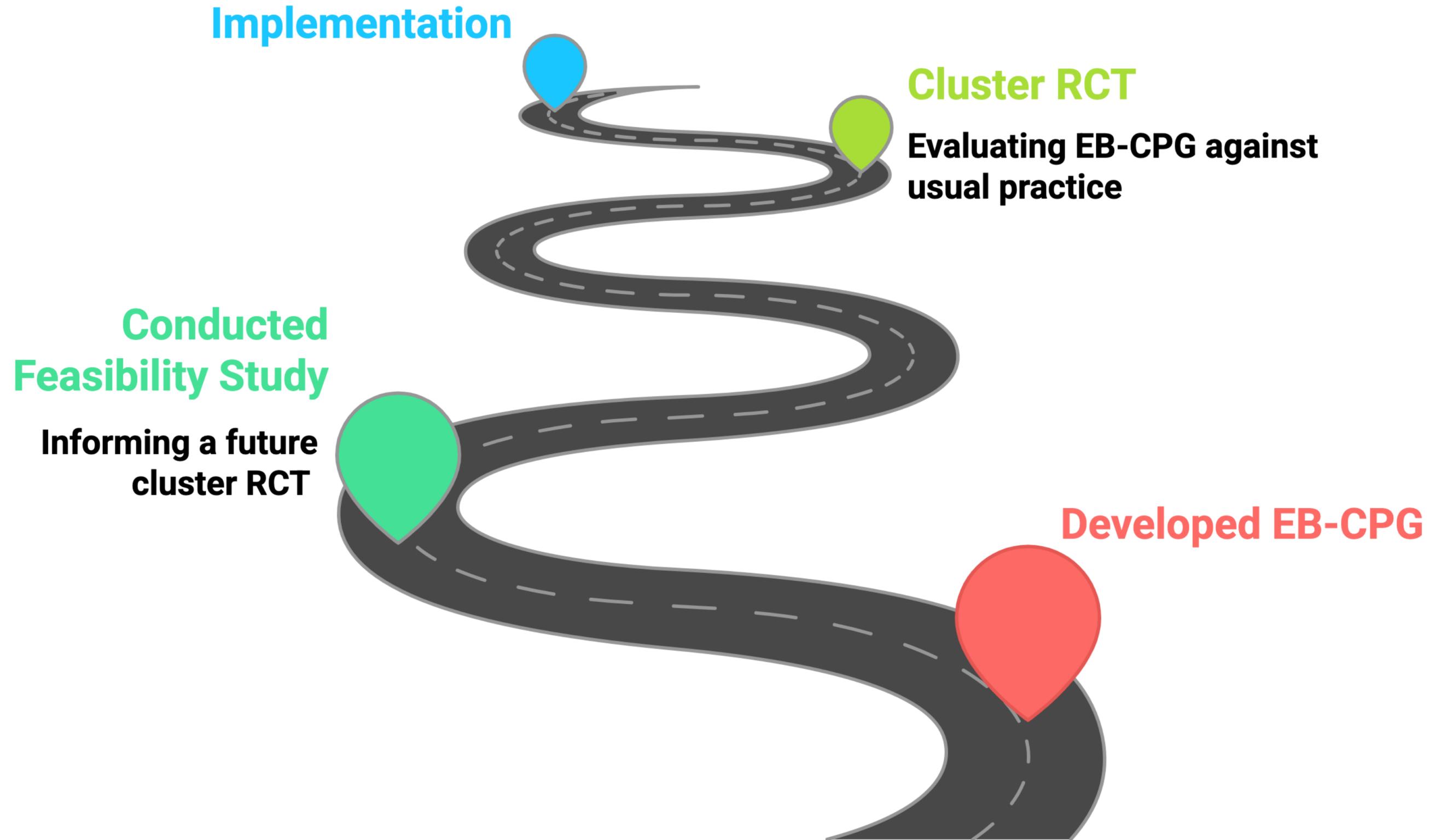
Concerns

No EB-CPG for managing T2DM.

Evidence-based clinical practice guideline



EB-CPG for Improving T2DM Management



Management of T2DM by Ayurvedic Practitioners



Intervention Group

Using our EB-CPG

VS



Control Group

**Usual clinical practice i.e.,
without a CPG**

High-Quality Comprehensive EB-CPG Development for T2DM Management

**Robust
Methodology
Usage**

Using the best
available scientific
evidence



**Key
Stakeholders
Involvement**



EB-CPG Covers



**T2DM
diagnosis**



**Treatment
targets**



**Lifestyle
advice**



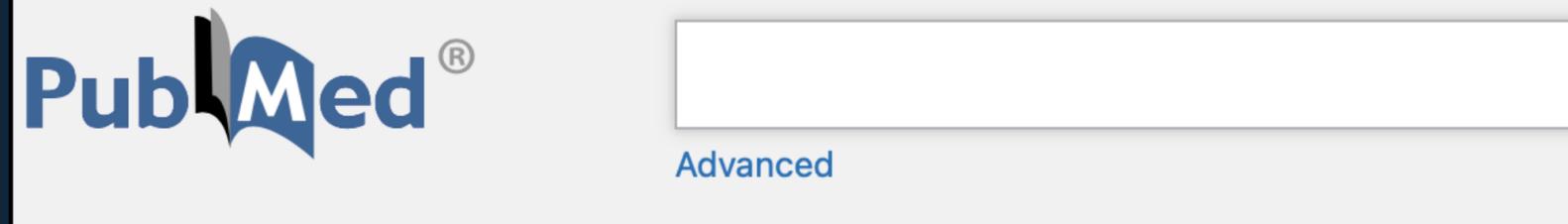
**Ayurvedic
antidiabetic
medicines**



**Complications
screening and
management**



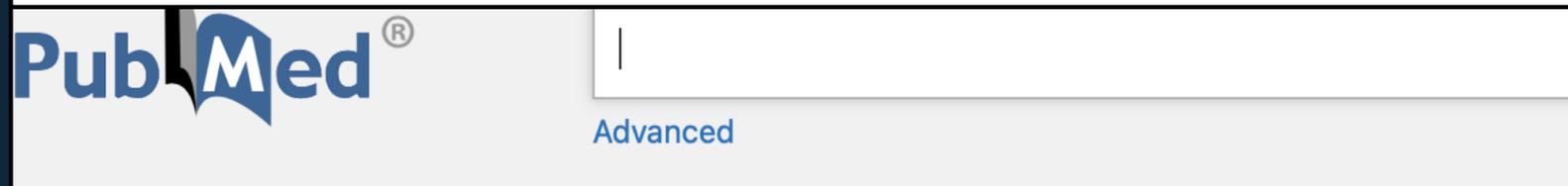
**Specialist
referrals if
needed**



Save

> Front Med (Lausanne). 2023 Jan 30:10:1043715. doi: 10.3389/fmed.2023.1043715. eCollection 2023.

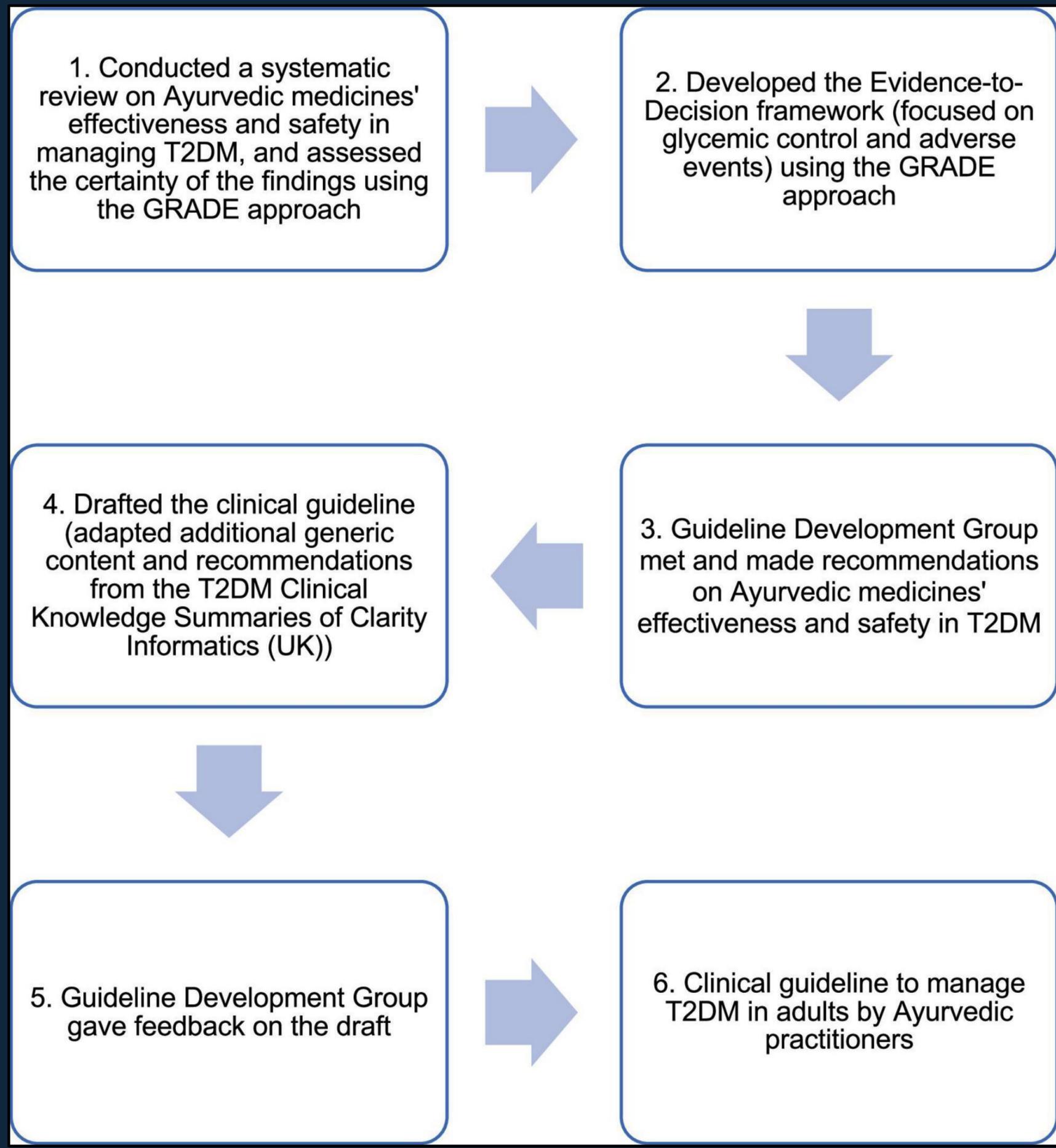
Development process of a clinical guideline to manage type 2 diabetes in adults by Ayurvedic practitioners



Save Email

> Front Pharmacol. 2022 Jun 8;13:821810. doi: 10.3389/fphar.2022.821810. eCollection 2022.

Effectiveness and Safety of Ayurvedic Medicines in Type 2 Diabetes Mellitus Management: A Systematic Review and Meta-Analysis



Support EB-CPG Uptake and Adherence



Training Sessions

Ayurvedic practitioners received regular training in EB-CPG usage, including role-playing and peer-led sessions.



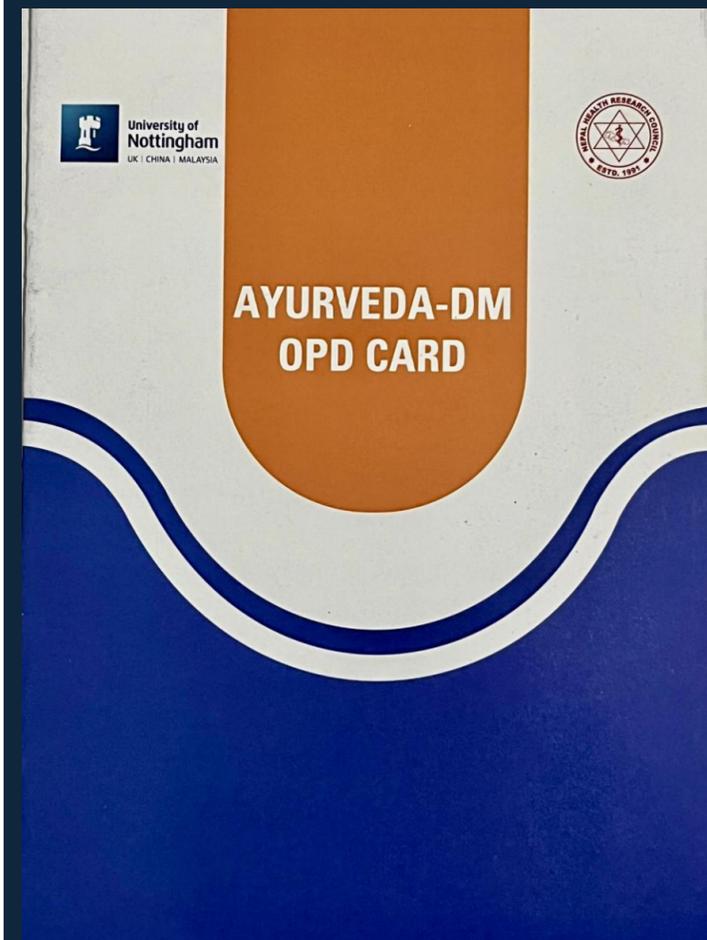
Structured Booklet

Ayurvedic practitioners received an EB-CPG-based structured booklet for writing case notes.



Free Medicine

An EB-CPG-recommended Ayurvedic antidiabetic medicine was provided free of charge to participants.



Feasibility Cluster RCT



Randomization

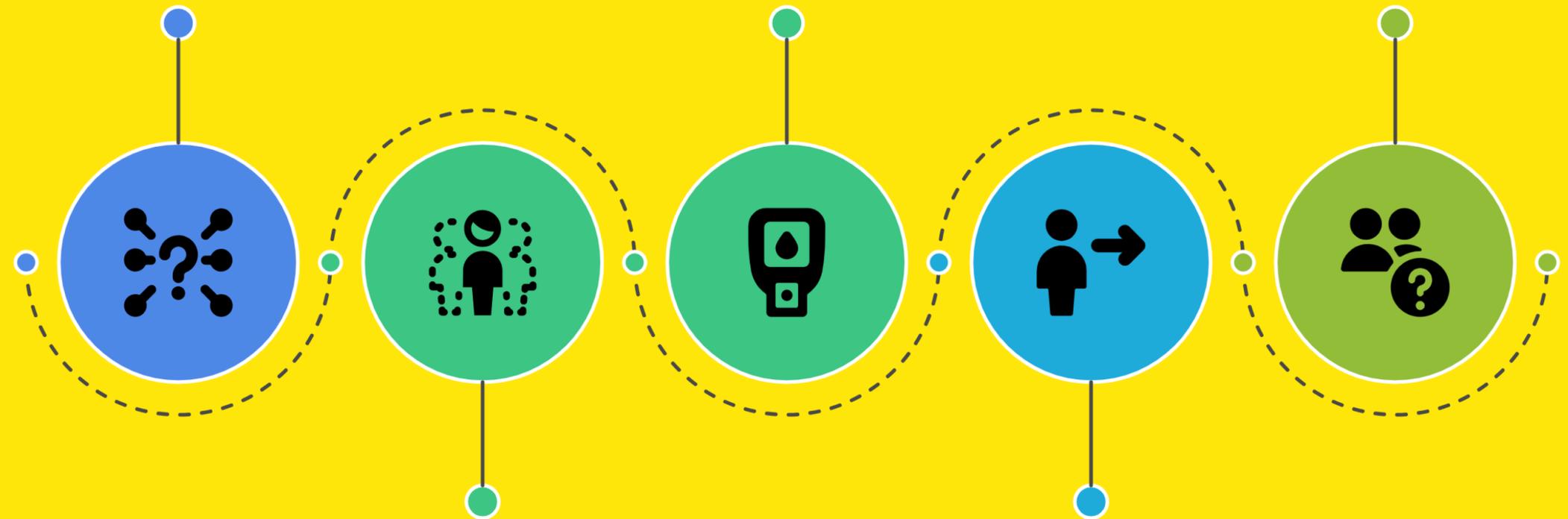
Ayurveda centers randomized into two groups by an independent statistician

Participant Recruitment

Adults with newly diagnosed T2DM recruited

Qualitative Interviews

Semi-structured interviews conducted with Ayurvedic practitioners and patients

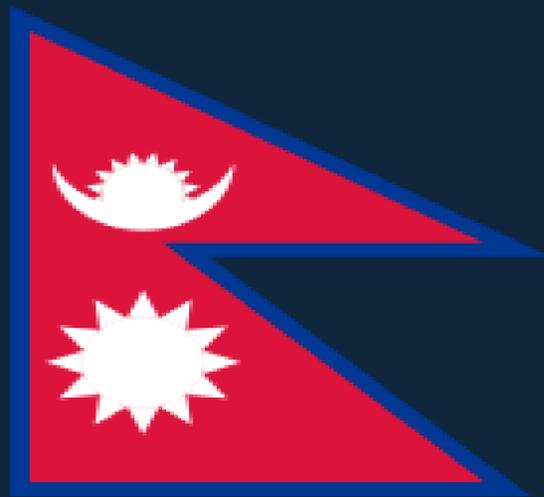


Blinding

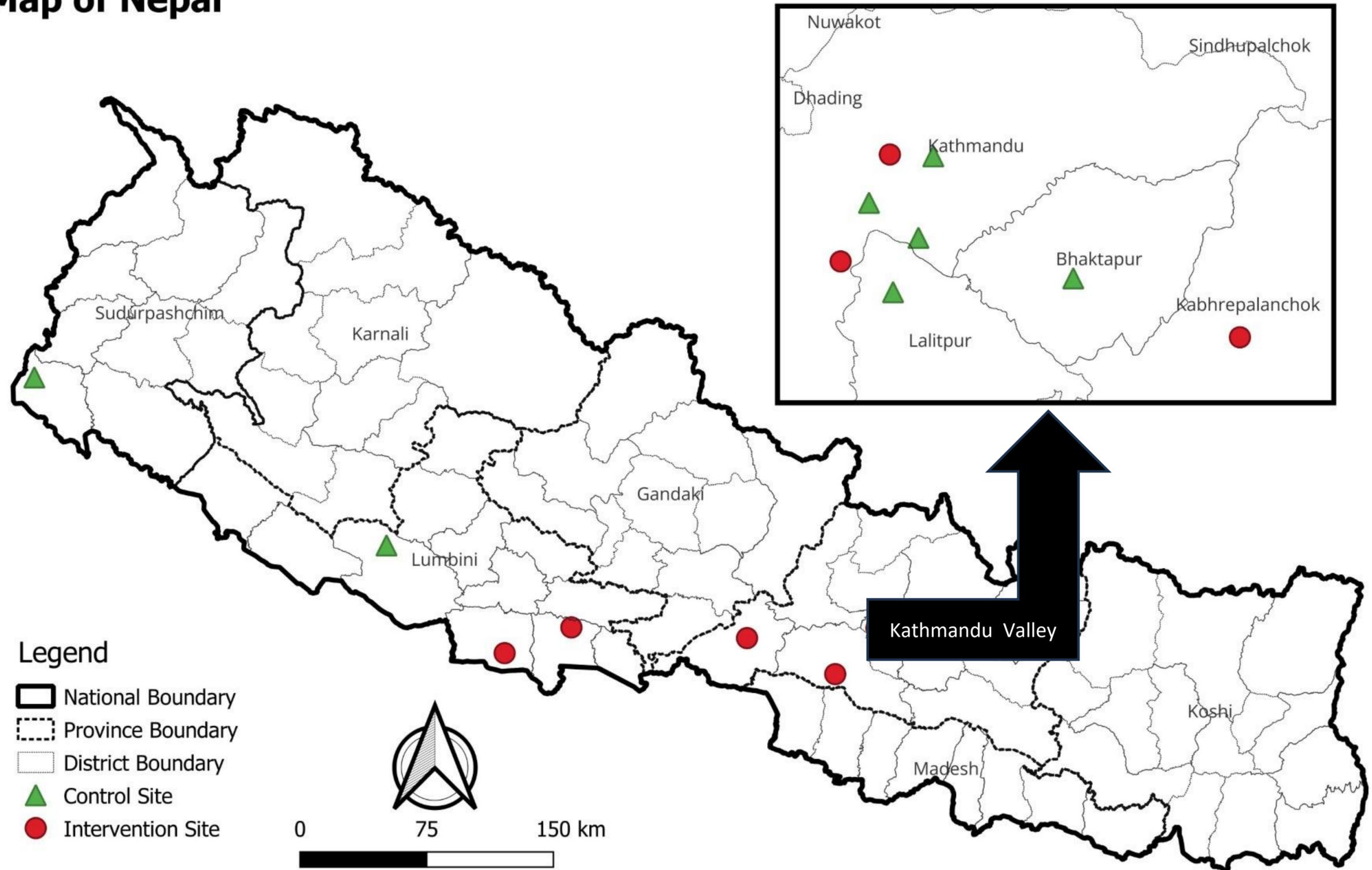
Data collectors and analyst blinded to group allocation

Follow-up

Participants followed up for 6 months



Map of Nepal



Enrollment

Assessed for eligibility
(15 clusters)

Excluded
(0 clusters)

Randomized
(15 clusters)

Allocation

Allocated to intervention (7 clusters)
Recruited patients (7 clusters)
(n=60 patients, mean (SD) cluster size=9
(3))
Did not recruit patients (0 clusters)

Allocated to control (8 clusters)
Recruited patients (7 clusters)
(n=61 patients, mean (SD) cluster size=9
(4))
Did not recruit patients (1 cluster left the
study at the onset)

Follow-up

Lost to follow-up (0 clusters)
Patients withdrew (n=5; mild dizziness
(1), wanted to use Western medicine (1),
no reason provided (3))
Site investigator withdrew (n=2; referred
to Western medicine for high HbA1c (1),
had planned cholecystectomy (1))
Patients lost to follow-up (n=2; stopped
responding to telephone calls)

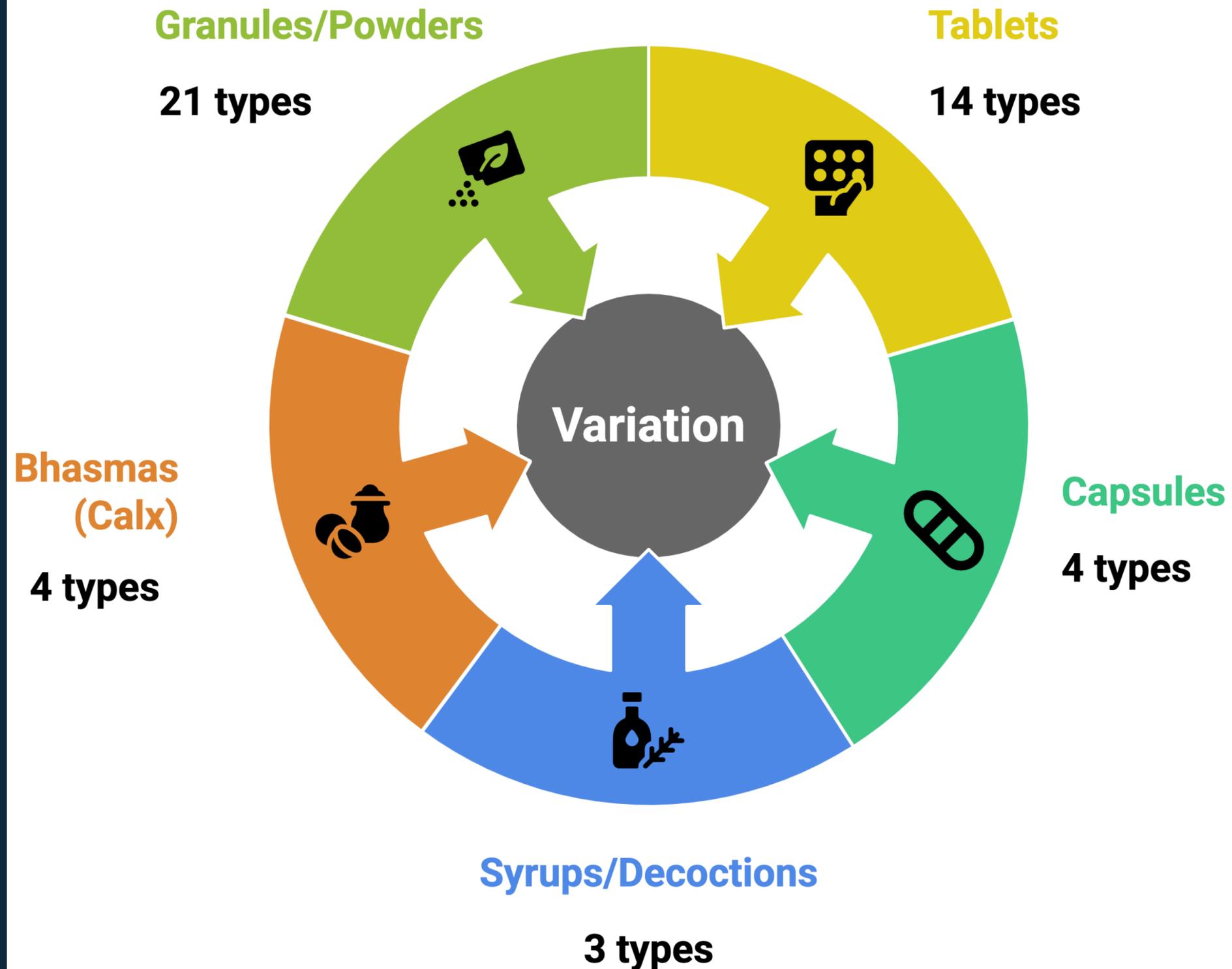
Lost to follow-up (0 clusters)
Patients withdrew (n=8; high liver
enzymes/advised by Western medicine
clinician (1), migrated to another country
(1), time constraints (1), wanted to use
Western medicine (2), long travel distance
(3))
Patients lost to follow-up (n=2; stopped
responding to telephone calls)

Analysis

Analyzed (7 clusters)
(n=60 patients, mean (SD) cluster size=9 (3))

Analyzed (7 clusters)
(n=61 patients, mean (SD) cluster size=9 (4))

Usual Care Ayurvedic Practitioners Prescribed Classical and Proprietary Medicines with Plant, Animal, and Mineral Ingredients – Single or Combined



Gap Between Clinical Practice and Evidence

What did the systematic review and meta-analysis find about certain medicines for T2DM?

Some were ineffective in controlling blood glucose, while others need more RCTs for effectiveness and safety.

Have all routinely prescribed medicines been evaluated in RCTs for T2DM?

Many have not been evaluated for glycemic control or safety in T2DM.

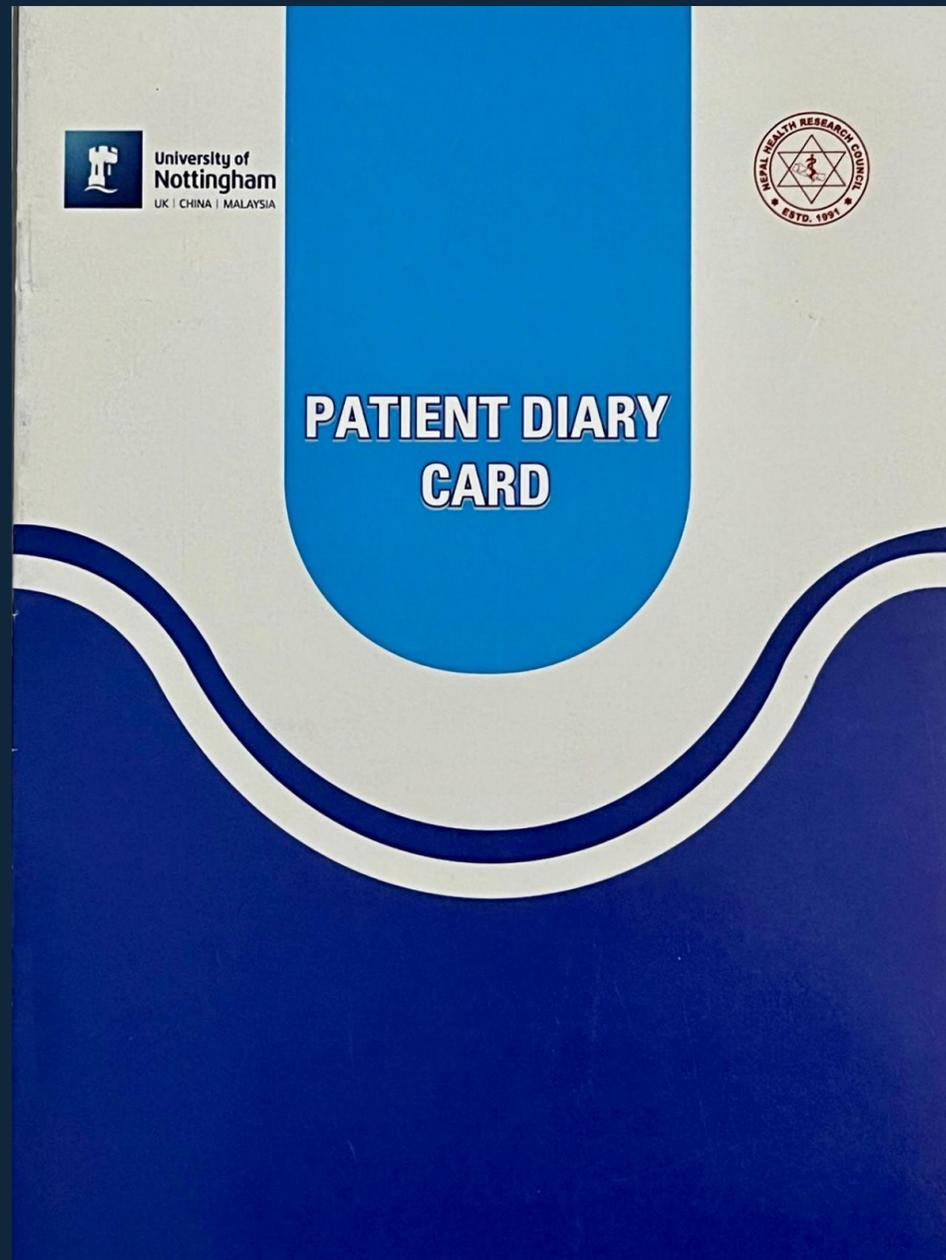


EB-CPG Adherence Among Intervention Group Ayurvedic Practitioners (N=7)

	Median (IQR)
Type 2 diabetes mellitus diagnosis	2 (1-2)
Treatment targets	1 (1-1)
Lifestyle advice	
<i>Diet</i>	1 (1-2)
<i>Exercise and physical activity</i>	1 (1-1)
<i>Alcohol intake</i>	2 (1-2)
<i>Smoking and drug misuse</i>	2 (1-2)
Ayurvedic antidiabetic medicine	1 (0-2)
Complications' screening and management	
<i>Retinopathy</i>	2 (1-2)
<i>Foot problems</i>	1 (1-2)
<i>Diabetic kidney disease</i>	1 (1-2)
<i>Cardiovascular risk factors</i>	1 (1-2)
<i>Peripheral and autonomic neuropathy</i>	2 (2-2)
<i>Hyperglycemia management</i>	N/A (no cases)
<i>Intercurrent illness management</i>	N/A (no cases)
<i>Hypoglycemia management</i>	N/A (no cases)
Advice on driving, insurance, fasting (including religious/sociocultural festivals), work, and holidays and travel	1 (1-2)

0=Not adhered to EB-CPG; 1=Partially adhered to EB-CPG; 2=Adequately adhered to EB-CPG.

EB-CPG Ayurvedic Medicine Compliance

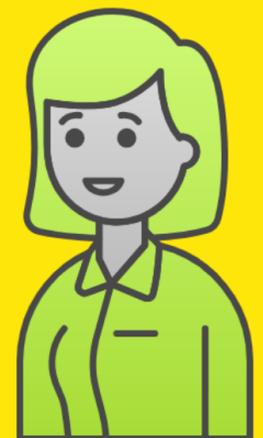
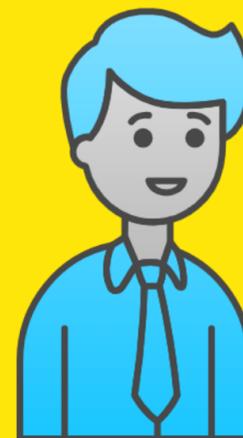


What was the median number of Ayurvedic antidiabetic medicine capsules not consumed by participants?

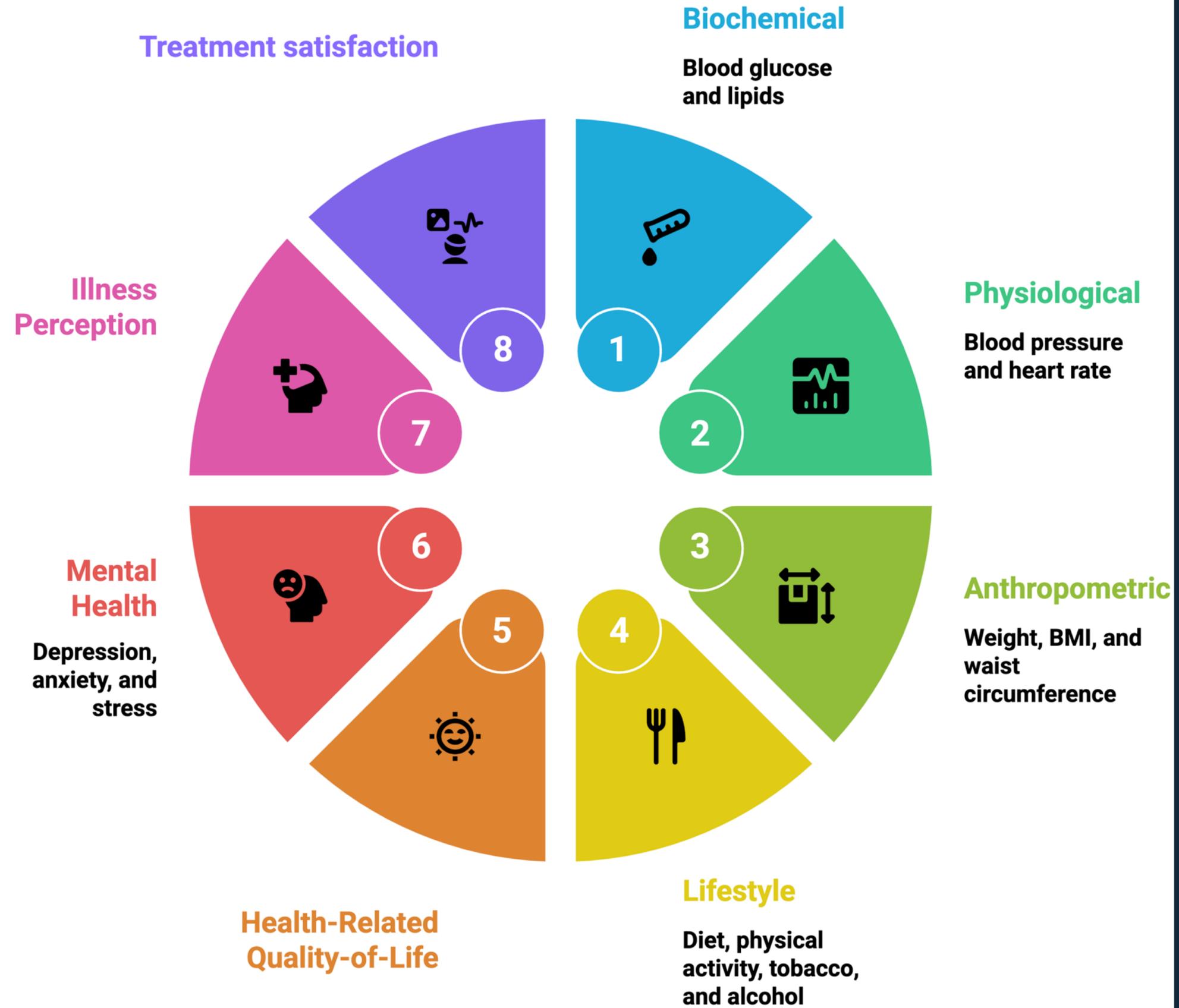
The median was 0 (0-10) capsules.

How many days did participants not consume the medicine over 6 months?

The median was 0 (0-2.5) days.



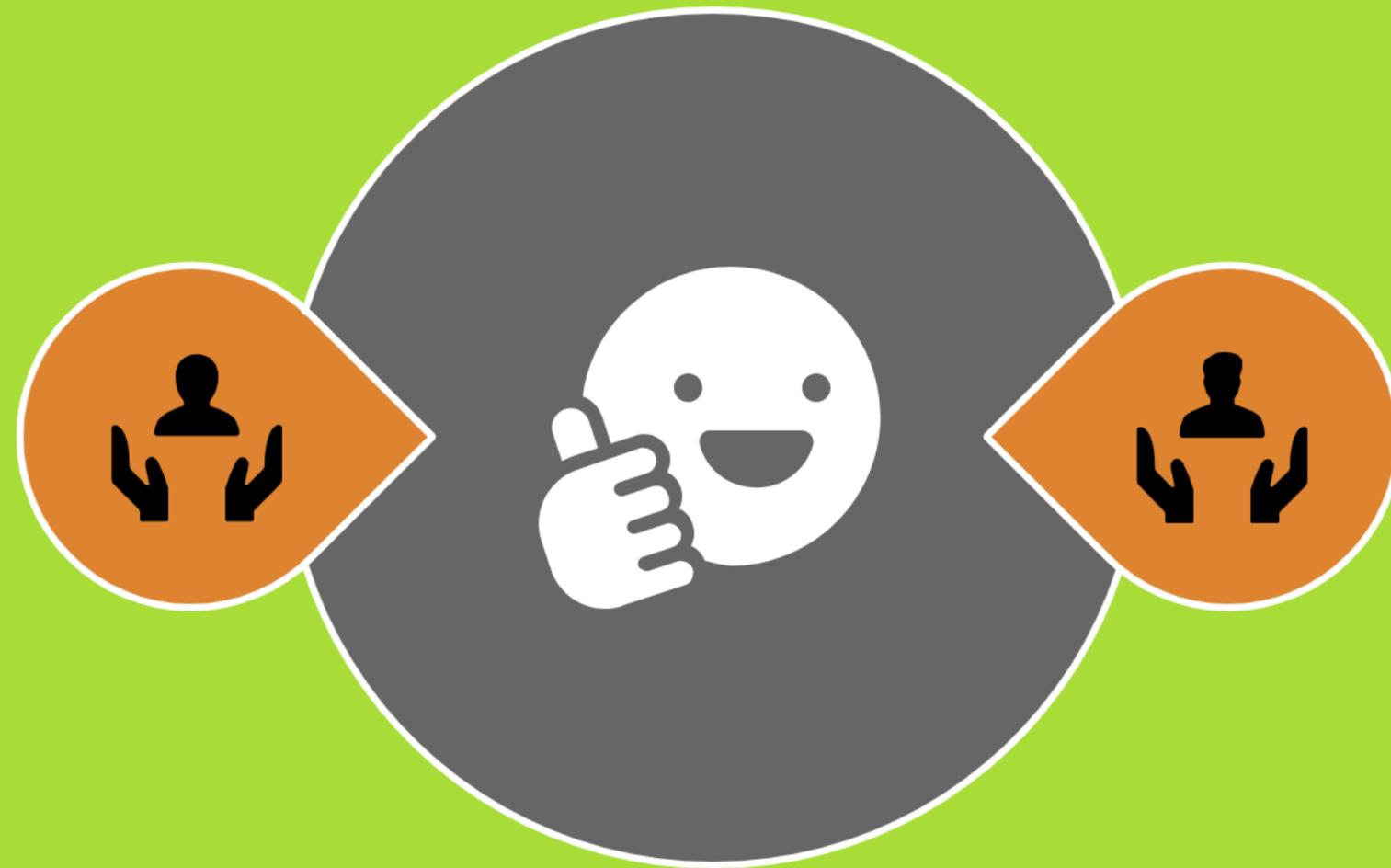
Comprehensive Assessment



Key Effectiveness Outcomes at 6 Months (at Cluster Level)

	Intervention		Control		
	Number of individuals	Mean (SD) of cluster means	Number of individuals	Mean (SD) of cluster means	Adjusted MD (95% CI)
Glycated hemoglobin (%)					
<i>Intention-to-treat analysis</i>	60	6.8 (1.3)	61	7.0 (1.2)	-0.09 (-0.55, 0.38)
<i>Complete case analysis</i>	50	7.1 (1.1)	51	7.2 (0.8)	-0.17 (-0.68, 0.34)
Fasting plasma glucose (mg/dL)					
<i>Intention-to-treat analysis</i>	60	122.2 (36.4)	61	120.2 (32.9)	-1.86 (-18.80, 15.09)
<i>Complete case analysis</i>	50	133.4 (34.6)	50	122.6 (13.2)	-3.85 (-26.93, 19.24)
Health-related quality-of-life – EQ-5D index score (<0 to 1)					
<i>Intention-to-treat analysis</i>	60	1.0 (0.1)	61	1.0 (0.2)	0.02 (-0.04, 0.07)
<i>Complete case analysis</i>	50	1.0 (0.0)	51	1.0 (0.1)	0.01 (-0.04, 0.06)

No Serious Adverse Events



Conclusion - Feasibility Trial



Success

Demonstrated successful recruitment, follow-up, and intervention adherence.



Next Step

A definitive trial for the intervention's effectiveness is feasible.



Interviewed Individuals (41)



Ayurvedic Practitioners

14 practitioners
were interviewed
from both
groups.



Patients

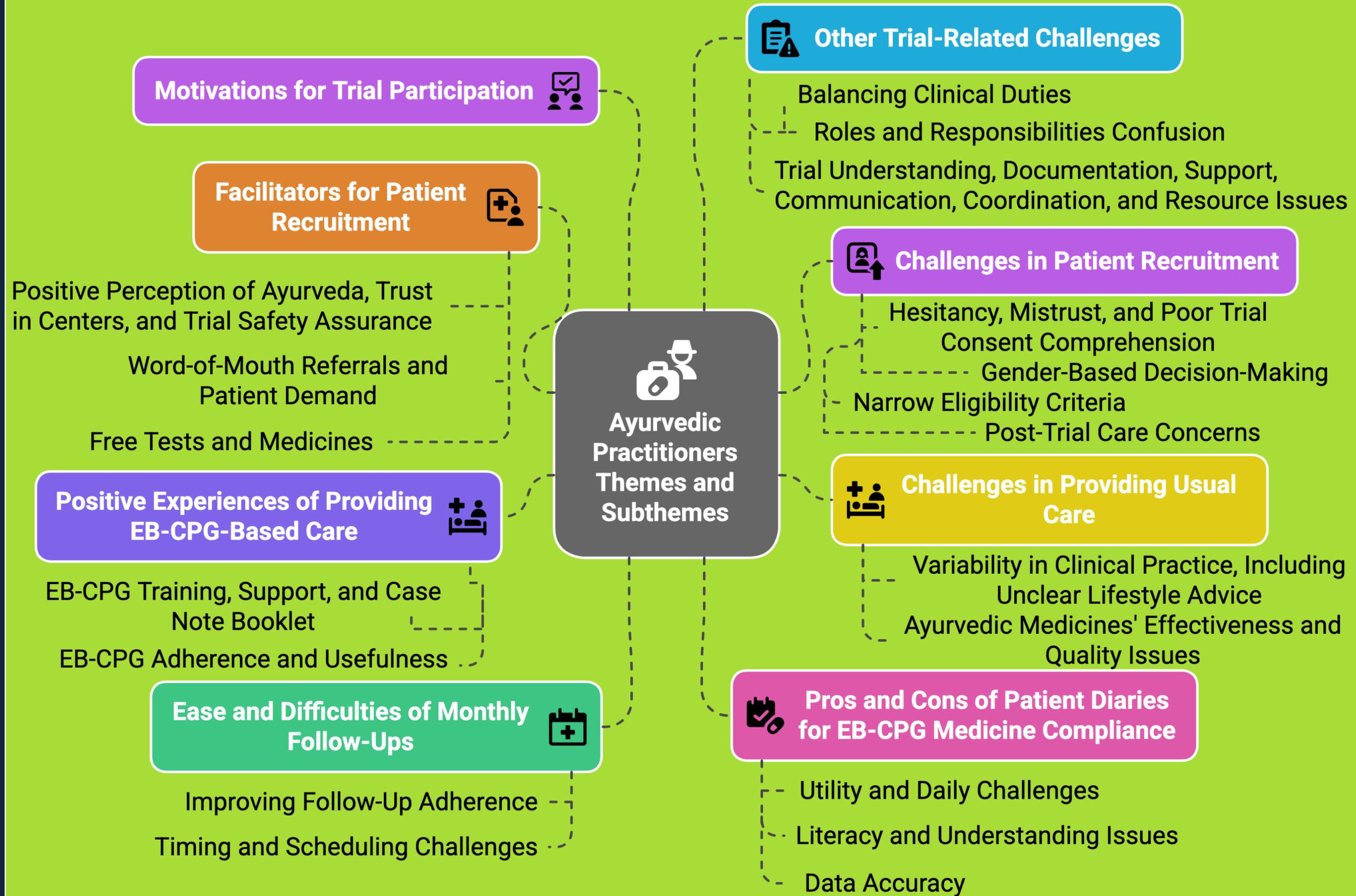
20 patients
were
interviewed
from both
groups.



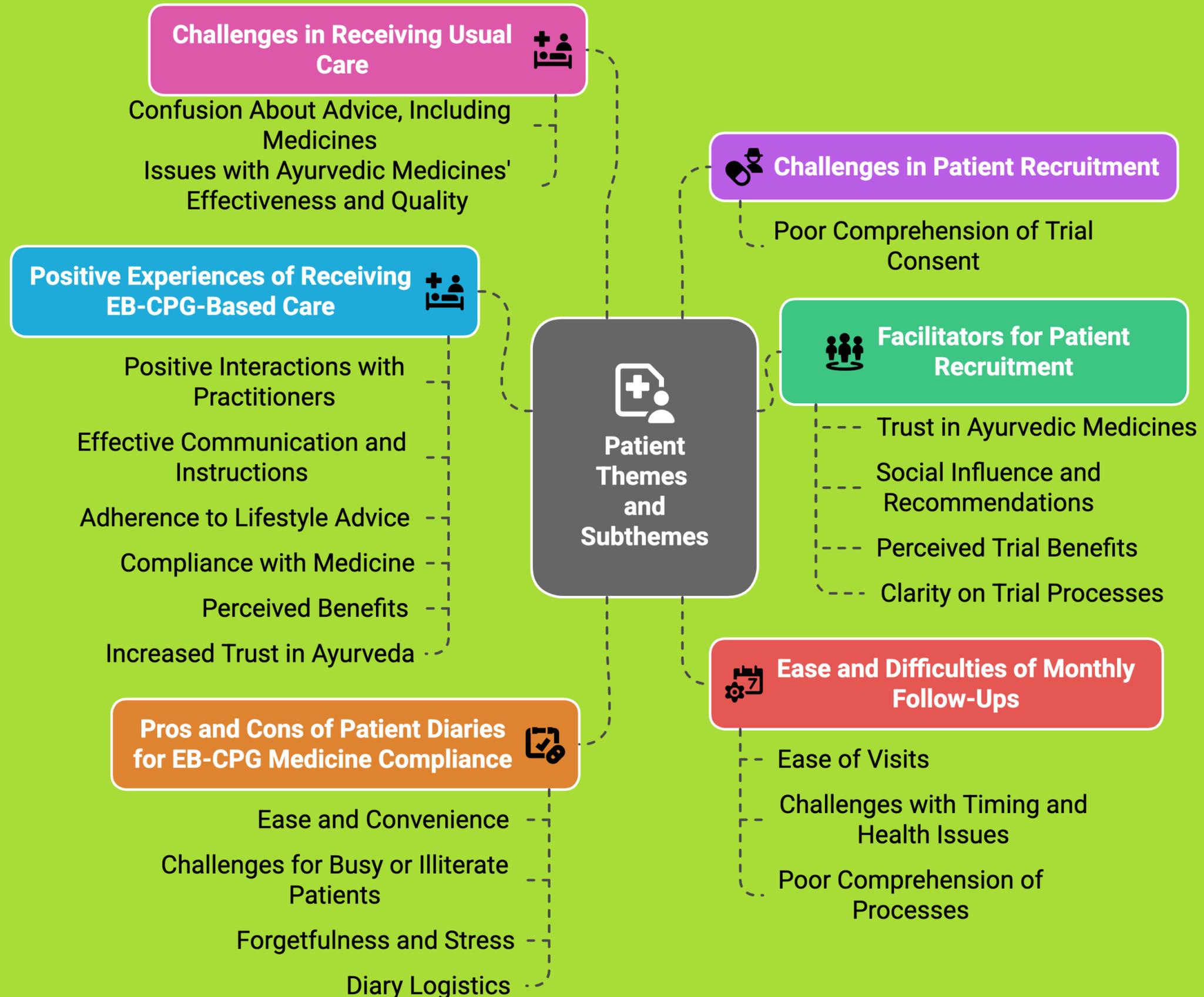
Declined or Withdrew

7 individuals
who declined
to participate
or withdrew
from the trial.

Experiences and Perspectives of Ayurvedic Practitioners



Experiences and Perspectives of Patients



Conclusion - Qualitative Study

Challenges Identified

Challenges related to trial conduct were identified for future improvement.



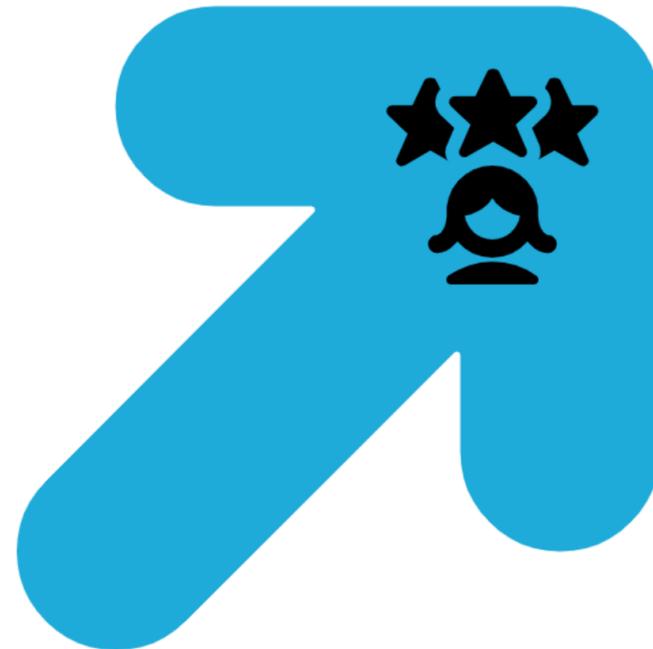
Positive Reception

The EB-CPG-based approach was well-received by participants.



Positive Experiences

Participants had largely positive experiences during the trial.



Benefits

The approach was considered more beneficial than usual practice.





Monitoring Visits



News ▶ UK & World News
Traditional Indian medicines found to treat diabetes
They can also help people manage their body weight, blood pressure and cholesterol
By **Gwyn Wright & Daniel Smith**
15:22, 8 JUN 2022 | UPDATED 15:23, 8 JUN 2022

Lifestyle > Health & Families

Traditional Indian Ayurveda effectively treats type 2 diabetes, study suggests

Researchers say Ayurvedic medicines help control blood sugar levels in patients

Kate Ng • Thursday 09

New Treatment for Type 2 Diabetes Found in Traditional Native Indian Medicine
July 15, 2022 · by Irina Aurelia Tit · 0

NEWS
Traditional Ayurvedic Medicines Can Help Control Blood Glucose: Study
Dr Rob Hicks, MB BS | Disclosures | 09 June 2022

MEDICINA AYURVEDICA ATTIVA CONTRO IL DIABETE DI TIPO 2

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The potential of Ayurvedic medicine

Traditional Indian Medicine can Treat Type 2 Diabetes
Several traditional medicines that are commonly used in South Asia were found to be effective in treating type 2 diabetes, reveals a new study, led by experts at the University of Nottingham

Traditional Native Indian Medicine Is Effective In Treatment Of Type 2 Diabetes, Says New Study
By **Ria Kakkad** (Drug Target Review)

Traditional native Indian medicine is effective in treatment of type 2 diabetes, says new study

Bem-Estar
Medicina ayurvédica pode ajudar pessoas com diabetes tipo 2, afirma estudo

THE EPOCH TIMES **EPOCH HEALTH**
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Health News | Research & Discoveries COVID News Health Care
Study Finds Traditional Indian Ayurvedic Medicines Improve Type 2 Diabetes Symptoms
HEALTH NEWS
Marina Zhang
Jun 14 2022



HEALTH

Traditional Native Indian Medicine is Effective in Treatment of Type 2 Diabetes, Says New Study



Ayurvedic medicine is safe & effective in treating type 2 diabetes patients

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Ayurvedic medicine is effective in blood sugar control in patients with type 2 diabetes, study finds

Study finds traditional Native Indian medicine effective treatment for type 2 diabetes

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Editor's Pick Traditional medicine

Traditional Ayurveda medicines treat type 2 diabetes – UK meta-analysis

Study Finds Traditional Native Indian Medicine Effective Treatment for Type 2 Diabetes

Medonet | Leky od A do Z | Ziola | Ziola mogą pomóc w cukrzycy

Ziola mogą pomóc w cukrzycy

研究：传统印度阿育吠陀药物可改善2型糖尿病

Tradycyjne indyjskie zioła mogą pomagać w cukrzycy

Traditional Indian Medicine can Treat Type 2 DIABETES

Traditional native Indian medicine is effective in treatment of type 2 diabetes, study finds



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Thank You

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