Unit 6. The Research Process

Unit 6: The Research Process

Learning Goals

By the end of this unit, you will be able to:

- Convert an area of interest into a **researchable problem**, question, and **testable hypothesis** with clear objectives.
- Plan **materials and methods** that are ethical, feasible, and statistically sound.
- Conduct **data collection, analysis, and interpretation** aligned to objectives.
- Draw **valid, generalisable conclusions** while acknowledging limitations.
- Write and present findings using **scientific reporting standards** suitable for BAMS-level work.

---

1) Selecting a Research Topic and Research Problem

1.1 From Topic → Problem → Question

- **Topic**: a broad area (e.g., "Ayurvedic management of osteoarthritis").
- **Research problem**: a **specific gap/uncertainty** that matters (e.g., "Unclear whether adding a standardised Abhyanga–Svedana + internal formulation to usual care improves function at 12 weeks").
- **Research question**: a precise, answerable formulation (e.g., **PICO**).

Useful filters

- **FINER**: Feasible, Interesting, Novel, Ethical, Relevant.
- **SMART objectives** later: Specific, Measurable, Achievable, Realistic, Time-bound.

Ayurveda-specific lens

- Ensure the problem is meaningful for **whole-system care** (diet, lifestyle, pañcakarma, formulations) and patient-important outcomes, not only surrogates.

1.2 Framing with PICO (or variants)

- **P**opulation: who and where (e.g., adults with knee OA in district hospital).
- **I**ntervention/Exposure: what you give/observe (e.g., standardised whole-system Ayurvedic package).
- **C**omparator: usual care, placebo, alternative regimen.
- **O**utcomes: function, pain, quality of life; safety.

Example PICO question:
"In adults with knee osteoarthritis (P), does adding a standardised whole-system Ayurvedic package (I) to usual care compared with usual care alone (C) improve WOMAC function at 12 weeks (O)?"

---

2) Reviewing the Literature

2.1 Purpose

- Understand **what is known**, where the gaps are, and which methods worked or failed.
- Define **outcomes**, **sample sizes**, and **risk-of-bias** concerns before you design.

2.2 Process (systematic mindset even for a narrative review)

1. **Scope and keywords**: use PICO terms and synonyms (e.g., “Abhyanga”, “Svedana”, “osteoarthritis”, “function”).
2. **Sources**: textbooks, theses, credible journals, trial registries, guidelines, and classical texts/commentaries for Ayurveda rationale.
3. **Inclusion/Exclusion**: populations, interventions, outcomes, designs, time window.
4. **Critical appraisal**: look for randomisation, concealment, blinding, attrition, selective reporting; for observational studies, assess confounding control.
5. **Synthesis**: summarise patterns, effect sizes, and gaps; state how your study adds value (e.g., pragmatic setting, better outcomes, fidelity measures).

Tip: Extract comparable **outcomes and time points** you will adopt; note **adverse events** and **herb–drug interactions** reported.

---

3) Formulating the Research Hypothesis and Objectives

3.1 Hypotheses

- **Null (H_0)**: no difference/association (e.g., “WOMAC function at 12 weeks is equal between groups”).
- **Alternative (H_1)**: difference/association exists (directional or non-directional).
  Hypotheses apply to **analytical** studies; purely descriptive studies may not need them.

3.2 Objectives

Write **SMART** objectives. Use **primary** and **secondary** objectives.

Example

- **Primary objective:** To compare change in WOMAC function at 12 weeks between whole-system Ayurveda + usual care vs usual care.
- **Secondary objectives:** pain, rescue analgesic use, sleep quality, *Agni* and *Bala* scales (validated), safety labs, acceptability.

Operational definitions: state exactly **how** each variable will be measured (tool, scale, timing).

---

4) Planning the Research (Materials and Methods)

4.1 Study Type and Design

Choose design by question and feasibility (see Unit 5):

- **Descriptive** (prevalence, case series),
- **Analytical observational** (cohort, case–control),
- **Interventional** (explanatory or pragmatic RCT, cluster RCT).
  For integrative care, **pragmatic**/cluster approaches are often appropriate.

4.2 Setting, Population, Eligibility

- **Setting:** OPD/IPD, district hospital Ayurveda unit.
- **Population:** inclusion and exclusion criteria (e.g., diagnostic criteria, age range, comorbidities).
- **Sampling:** probability or consecutive sampling; for cluster trials, define clusters (PHCs/clinics).

4.3 Variables and Scales

Variable type	Examples	Scale	Notes
Primary outcome	WOMAC function change	Continuous	MCID informs sample size
Secondary outcomes	Pain VAS, PGIC, *Agni* scale, *Bala* scale	Continuous/ordinal	Use validated instruments
Safety	AEs, LFTs, creatinine	Categorical/continuous	Define AE reporting windows
Covariates	Age, sex, BMI, baseline severity, *prakṛti*	Various	Pre-specify in analysis plan

4.4 Sample Size

- Based on **primary outcome**: expected mean difference (or RR), SD, α (usually 0.05), **power** (≥80%), and **MCID**.
- For cluster trials, adjust for **ICC** and cluster size.
- For qualitative components, plan for **saturation** rather than numeric power.

4.5 Randomisation, Concealment, Blinding (if trial)

- **Randomisation**: simple/block/stratified/minimisation; central sequence.
- **Concealment**: sequentially numbered, opaque, sealed envelopes (SNOSE) or central allocation.
- **Blinding**: where feasible; if not, ensure blinded outcome assessment and objective measures.

4.6 Intervention Standardisation (Ayurveda)

Document **diagnostic framework** (*doṣa, dūṣya, srotas, agni*), and **components**:

- **Abhyanga–Svedana** sequence (media, duration, frequency).
- **Internal formulations** (botanical identity, dose, *anupāna*, manufacturer or pharmacy SOP, quality certificates).
- **Pathya–Apathya** counselling scripts.
- **Fidelity tools**: checklists, session logs, adherence diaries.

4.7 Data Collection Tools and Quality

- Pilot-test case report forms (CRFs) and questionnaires.
- Train assessors; inter-rater reliability if subjective scales are used.
- Data dictionary; coding plan; timelines.

4.8 Ethics and Registration

- Obtain **IEC/IHEC** approval.
- **Trial registration** before first participant for interventional studies.
- **Consent documents** in local language; safety monitoring plan; compensation for injury as per norms.
- **Privacy**: de-identification, secure storage, access control.

---

5) Conducting the Research (Data Collection, Analysis, Interpretation)

5.1 Data Collection

- Recruitment log; screen failures and reasons.
- Baseline assessments as per **Dasavidha-parīkṣā** analogues (constitution, strength, etc.) where relevant, using validated modern measures.
- **Intervention delivery** monitoring (attendance, dose changes with rationale).
- **AE/SAE** detection and reporting.

Common pitfalls: protocol deviations, missing follow-ups, uncalibrated instruments, untrained assessors.

5.2 Data Management

- Double data entry or validation rules; routine **data cleaning** (range checks, missingness patterns).
- Pre-specified **handling of missing data**: ITT with multiple imputation if appropriate; sensitivity analyses.

5.3 Statistical Analysis (aligned to objectives)

- **Descriptive**: mean (SD), median (IQR), counts (%), baseline comparability table.
- **Primary analysis**:
  - Continuous outcomes: t-test/ANCOVA (adjust for baseline), or mixed-effects models for repeated measures.
  - Binary outcomes: risk ratio with 95% CI (log-binomial/Poisson with robust SE).
  - Time-to-event: Kaplan–Meier, Cox model (hazard ratio).
- **Adjustments**: pre-specified covariates; cluster effects (mixed models or GEEs).
- **Effect size & precision**: always report **95% CI**; do not rely only on p-values.
- **Clinical significance**: interpret relative to **MCID** and patient values.

5.4 Qualitative Analysis (if mixed-methods)

- Thematic analysis: coding framework, constant comparison, triangulation, reflexivity notes.
- Integrate with quantitative findings to explain **adherence, acceptability, and context**.

5.5 Interpretation

- Distinguish **statistical** from **clinical** significance.
- Consider **bias**: selection, measurement, confounding; discuss how design/analysis addressed them.
- Evaluate **external validity**: can results be generalised to other centres or populations?
- Balance **benefits vs harms** and **cost/feasibility** for scale-up.

---

6) Drawing Conclusions

A good conclusion answers the **original question**, states **what is new**, and is **honest about limits**.

Structure

1. **Primary finding** with effect size and CI (e.g., “Addition of whole-system Ayurveda improved WOMAC function by 7.5 points [95% CI 3.2–11.8] at 12 weeks vs usual care.”).
2. **Clinical meaning** (compare to MCID; patient-important perspective).
3. **Safety** summary.
4. **Limitations** (e.g., single site, partial unblinding, adherence variability).
5. **Implications** (practice, training, policy) and **next steps** (multicentre pragmatic replication, cost-effectiveness).

Avoid **overgeneralisation** and **causal claims** beyond the design’s strength.

---

7) Reporting of Research (Scientific Writing)

7.1 IMRaD Structure

- **Title**: concise, informative, includes design (e.g., “Pragmatic Randomised Trial…”).
- **Abstract**: structured summary (background, methods, results with key numbers, conclusion).
- **Introduction**: the **why**—gap and objective; 3–5 paragraphs.
- **Methods**: the **how**—design, setting, participants, interventions/exposures, outcomes, sample size, randomisation, blinding, analysis plan, ethics/registration.
- **Results**: the **what**—participant flow (diagram), baseline table, primary and secondary outcomes (effect sizes, CIs),

harms, sensitivity analyses.
- **Discussion**: interpret, compare with literature, strengths/limitations, implications, future research.
- **Conclusion**: 2–4 crisp lines echoing the objective.
- **Declarations**: authorship roles (CRediT), funding, conflicts of interest, data availability, acknowledgements.

7.2 Tables and Figures

- Keep **self-contained titles/footnotes**; define abbreviations.
- Use **CONSORT/STROBE/PRISMA**-aligned flow diagrams and checklists as appropriate.
- For Ayurveda interventions, include a **fidelity table** (components, frequency, adherence).

7.3 Language and Ethics of Writing

- Precise, neutral tone; avoid exaggeration.
- Credit prior work; avoid plagiarism and **salami slicing**.
- Include **trial registration** and **IEC approval** identifiers in the manuscript.
- Ensure patient privacy in case reports; get explicit consent for identifiable images.

Quick Checklists

Before you start

- FINER satisfied; PICO defined; SMART objectives drafted.
- Literature reviewed; gaps identified; outcomes chosen; harms noted.
- Design chosen; sample size estimated; analysis plan sketched.
- IEC approval; registrations completed; SOPs and CRFs piloted.

While conducting

- Recruit per eligibility; log screening; ensure allocation concealment (if trial).
- Deliver intervention per protocol; track fidelity and adherence.
- Monitor AEs/SAEs; conduct blinded assessments where feasible.
- Clean data; document deviations; stick to analysis plan.

Before submitting

- Results reported with effect sizes and 95% CIs; primary outcome consistent with registration.
- Limitations acknowledged; conclusions proportionate.
- Checklists (CONSORT/STROBE/PRISMA) attached; COI and funding disclosed.

Assessment

A. Multiple-Choice Questions (MCQs)

1. The **best first step** after choosing a broad topic is to:
   A) Start recruiting participants
   B) Draft a SMART primary objective after a structured literature review
   C) Write the conclusion
   D) Conduct post-hoc subgroup analyses
   Answer: B
2. The **primary outcome** should be selected mainly because it:
   A) Is easy to measure
   B) Has the largest expected p-value

C) Reflects patient-important benefit and aligns with the main objective
D) Is cheapest
Answer: C

3. **Allocation concealment** protects against:
A) Detection bias
B) Selection bias at enrolment
C) Attrition bias
D) Performance bias
Answer: B
4. Handling **missing data** in an ITT analysis most appropriately involves:
A) Deleting all incomplete cases
B) Multiple imputation/sensitivity analysis as pre-specified
C) Guessing values
D) Ignoring the issue
Answer: B
5. A result is **clinically significant** when:
A) $p < 0.05$ regardless of magnitude
B) The CI excludes the null
C) The effect meets or exceeds the **MCID** and matters to patients
D) The sample is large
Answer: C
6. In mixed-methods, interviews conducted to explain surprising quantitative results correspond to:
A) Convergent parallel design
B) Explanatory sequential design
C) Exploratory sequential design
D) Case–control design
Answer: B
7. Pre-specifying **secondary outcomes** is important because it:
A) Allows selective reporting later
B) Clarifies multiplicity and prevents data dredging
C) Replaces the need for a primary outcome
D) Eliminates blinding needs
Answer: B
8. For a cluster RCT, the sample size must account for:
A) Response rate only
B) Intra-cluster correlation (ICC)
C) Only baseline imbalance
D) None of the above
Answer: B
9. A sound **conclusion** primarily:
A) Restates the introduction verbatim
B) Makes claims beyond data
C) Summarises the primary finding with effect size and CI, limitations, and implications
D) Focuses on p-values alone
Answer: C
10. In reporting, the **Methods** section should always include:
A) Only the successful parts
B) Outcome definitions, sample size, randomisation/concealment, and analysis plan
C) Opinions of the PI on Ayurveda
D) Funding alone
Answer: B

B. Short-Answer Questions (SAQs)

1. Define **research problem**, **research question**, and **hypothesis** with one example each in osteoarthritis knee.
2. List the steps of a **rigorous literature review** and state how they influence sample size and outcome choice.

3. Write a **primary objective** and **two secondary objectives** for a pragmatic trial of whole-system Ayurveda for dyspepsia.
4. Outline a **data quality plan** for an OPD-based cohort (training, calibration, CRF design, data checks).
5. Differentiate **statistical** and **clinical** significance with an example using pain VAS.

C. Long-Answer Questions (LAQs)

1. **Plan a complete methods section** for a cluster RCT evaluating the addition of Pathya counselling + Abhyanga–Svedana to usual care for chronic low back pain across 10 PHCs. Include design, eligibility, intervention, fidelity, outcomes, sample size (with ICC), randomisation, analysis, ethics, and registration.
2. **Write a Discussion** template for negative or null results in an Ayurveda trial, covering possible reasons (insufficient dose/frequency, adherence, measurement timing), implications, and future research directions without overstating.

D. Structured Task (Applied)

You have run a pragmatic RCT of a standardised whole-system Ayurvedic package for knee OA. The adjusted mean difference in WOMAC function at 12 weeks is **6.0 (95% CI 1.2–10.8)**, MCID is **5**, AE rates are similar.
Tasks:
a) Interpret **statistical** and **clinical** significance.
b) Draft two **conclusion sentences** suitable for a journal.
c) List **three limitations** and **two policy implications**.

Take-Home Messages

- Start with a **precise, patient-relevant question**; let **design and methods** follow the question.
- Pre-specify **outcomes, sample size, and analysis**; keep fidelity and data quality high.
- Interpret with **effect sizes, CIs, and MCID**; be transparent about limitations.
- Report using **IMRaD** and recognised guidelines; ensure ethics and registration are visible.

End of Unit 6.