BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: IMSC **SEMESTER : IX**
BRANCH: CQEDS **SESSION : MO/2025**

SUBJECT: ED503 RANDOMIZED CONTROL TRIALS

TIME: 3 Hours **FULL MARKS: 50**

INSTRUCTIONS:
1. The question paper contains 5 questions each of 10 marks and total 50 marks.
2. Attempt all questions.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

			CO	BL
Q.1	Read the following case carefully and answer the questions given at the end.	[10]	1	5

A hospital research team evaluated a counselling-plus-diet-tracking programme for newly diagnosed hypertensive adults. Eligible patients were informed that the hospital was studying different care pathways and that they might receive any of them. Before obtaining consent for a specific pathway, each patient was assigned to either the counselling programme (group A) or standard care (group B) using a concealed allocation list held by the trial coordinator.

The coordinator did not assign patients individually. Instead, allocations were taken from small sealed sets, each containing a fixed mix of counselling and usual-care labels. When one set was exhausted, the next sealed set was opened, keeping group sizes closely balanced during recruitment.

After assignment, patients allocated to counselling were approached by a research nurse, given full information about the programme, and asked to consent to receive it. Patients assigned to usual care were separately approached and asked to consent to continue with standard care and allow their data to be used. Those who refused their assigned pathway continued with whichever care plan they preferred, but their outcomes were still recorded.

Blood pressure at routine visits was measured by laboratory technicians who were unaware of group assignments. Data collectors and analysts worked independently from the clinical team. The primary outcome was systolic blood pressure at 12 weeks.

(i) Identify the type of RCT design used in this study. Which features of the case support your conclusion?
(ii) What type of blinding was used? Who was blinded, who was not, and how might this affect bias?
(iii) Identify the randomization method used for assignment of participants to each group.
(iv) *"Those who refused their assigned pathway continued with whichever care plan they preferred, but their outcomes were still recorded."* Will there be any biases in the result if the refusal rate and inter-group migration (crossovers/contamination) vary between the groups? Discuss.
(v) How does Intention-to-treat (ITT) analysis vary as-treated analysis (ATA) in this RCT? Which one will be better if the inter-group migration is not substantial? Justify your answer.

Q.2(a)	Discuss elaborately general threats to an RCT with respect to compliance, attrition, spillovers and evaluation-driven effects.	[6]	2	4

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Q.2(b) A researcher wants to estimate the proportion of employees in a company who have ever violated data-security rules ($\hat{\pi}$). Because employees may hesitate to answer honestly, the Unrelated Question Technique (UQT) is used. Each participant is randomly asked either the sensitive question ("Have you ever violated a data-security rule at work?") with probability p, or an unrelated question ("Is your mother's birthday in July-December?") with probability 1-p, and the true prevalence of the unrelated question is unknown.
To identify both unknown proportions, the sample is divided into two independent groups:
Group 1: receives the sensitive question with probability p1=0.40, and the observed "Yes" proportion is 0.520.
Group 2: receives the sensitive question with probability p2=0.65, and the observed "Yes" proportion is 0.470.
Using these values under the UQT framework, estimate the prevalence of data-security violations in the company ($\hat{\pi}$). [4] 2 4

Q.3 A public-health research team is developing a 4-item questionnaire to assess 'perceived stress' among community health workers in a district hospital. Identification of stress is done through worker's responses on 4 items and also through independent assessment by two domain experts who classify workers as "Yes" (the worker is stressed) or "No" (not stressed). The relevant data from the pilot study are given below: [10] 3 4

Worker sl. No.	Worker's response on each item				Expert's independent assessment	
	Item-1	**Item-2**	**Item-3**	**Item-4**	**Expert A**	**Expert B**
1	3	4	3	4	Yes	Yes
2	2	3	2	3	No	No
3	4	5	4	3	Yes	No
4	3	3	3	3	No	No
5	5	4	5	4	Yes	Yes
6	1	2	1	2	No	No
7	4	1	4	3	Yes	Yes
8	2	2	2	2	No	No
Note: 1-Lowest, 5-Highest for all four items assessing stress at different levels						

Calculate:
(i) A measure of internal consistency among the items measuring different aspects of stress. Interpret the result.
(ii) A measure of inter-rater reliability. Interpret the result.

Q.4 A team of biomedical researchers launched the *NutriHeart Trial* in Sundarpur, a remote rural district with high rates of illiteracy and limited access to healthcare. The study aimed to test a new dietary supplement claimed to reduce the risk of cardiac events. The supplement had already shown strong benefits in early pilot studies, and some investigators privately believed it was clearly superior to existing treatment options. Despite this, participants were randomized into two groups: the intervention group received the supplement, while the control group received a placebo, even though a standard, government-approved supplement with known benefits was available. [10] 4 5

Recruitment was conducted through local community leaders who encouraged villagers to "support the project." Many participants, including older adults and agricultural laborers, signed the consent form using thumbprints without being fully informed of the trial procedures or risks. Some were told only that the study was "good for the village," without explanation of randomization or the possibility of receiving a placebo.

The study also excluded pregnant women, even though the supplement had already been shown to be safe in pregnancy. Several pregnant women expressed interest in participating because of promised free health check-ups, but they were denied enrollment without an evidence-based justification.

During the trial, several participants from marginalized tribal communities were enrolled without adequate culturally appropriate counseling. Many believed participation was linked to continued access to routine health services provided temporarily by the research team. Meanwhile, the research team continued the trial despite accumulating data that clearly showed a strong advantage of the supplement.

After the trial concluded, the research team did not return to share results with the community or offer continued access to the beneficial supplement for participants who had been in the placebo group.

Identify and discuss all ethical violations in the above RCT.

Q.5 A district hospital is evaluating two treatments for acute migraine relief: [10] 5 4

Treatment A: A newly formulated fast-dissolving analgesic.

Treatment B: A standard oral analgesic used routinely in the hospital. Early observational records suggest Treatment A might act faster, but evidence is inconclusive, motivating an RCT.

Patients are allocated sequentially to two treatments (A and B). P(*) denotes the probability of assigning a patient to treatment *.

(i) If a simple randomization was adopted by tossing a fair coin (Head= Treatment A, Tail= Treatment B). Calculate P(A) and P(B) using this rule.

(ii) To ethically increase the chance that patients receive the better treatment as evidence accumulates, the hospital wants to use response-adaptive randomization. Calculate P(A) and P(B) using Bayesian Response-Adaptive Randomization (BRAR). Take Beta (1,1) prior.

(iii) If Randomized Play-the-Winner (RPW) urn design is adopted, calculate P(A) and P(B).

Show all the relevant formulae and steps. Present the final result in a tabular format given below:

Patient sl. No.	Assigned	Outcome	Simple Randomization		BRAR		RPW	
			P(A)	P(B)	P(A)	P(B)	P(A)	P(B)
1	A	Success						
2	B	Failure						
3	A	Success						
4	A	Success						
5	B	Success						
6	A	Success						
7	B	Failure						
8	B	Failure						

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