W1-2-60-1-6

JOMO KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY

UNIVERSITY EXAMINATIONS 2023/2024

MASTER OF SCIENCE IN EPIDEMIOLOGY

PEH-3103: EPIDEMIOLOGICAL METHODS

DATE: AUG 2024 **TIME: 3 HOURS**

INSTRUCTIONS: ANSWER ANY FOUR QUESTIONS

1) Read the following results section of an abstract and answer the questions that follow:

Results: Between 2016 and 2017, we randomised 392 women aged ≥ 18 years who had been diagnosed with breast cancer from 17 breast cancer centres across England: 196 (50%) to the usual-care group and 196 (50%) to the exercise group. Ten participants (10/392; 3%) were withdrawn at randomisation and 32 (8%) did not provide complete baseline data. A total of 175 participants (89%) from each treatment group provided baseline data. Participants' mean age was 58.1 years (standard deviation 12.1 years; range 28-88 years). Most participants had undergone axillary node clearance surgery (327/392; 83%) and 317 (81%) had received radiotherapy. Uptake of the exercise treatment was high, with 181 out of 196 (92%) participants attending at least one physiotherapy appointment. Compliance with exercise was good: 143 out of 196 (73%) participants completed three or more physiotherapy sessions. At 12 months, 274 out of 392 (70%) participants returned questionnaires. Improvement in arm function was greater in the exercise group [mean Disabilities of Arm, Hand and Shoulder questionnaire score of 16.3 (standard deviation 17.6)] than in the usual-care group [mean Disabilities of Arm, Hand and Shoulder questionnaire score of 23.7 (standard deviation 22.9)] at 12 months for **intention-to-treat** (adjusted mean difference Disabilities of Arm, Hand and Shoulder questionnaire score of -7.81, 95% confidence interval -12.44 to -3.17; p = 0.001) and **complier-average causal effect analyses** (adjusted mean difference -8.74, 95% confidence interval -13.71 to -3.77; p ≤ 0.001). At 12 months, pain scores were lower and physical health-related quality of life was higher in the exercise group than in the usual-care group (Short Form questionnaire-12 items, mean difference 4.39, 95% confidence interval 1.74 to 7.04; p = 0.001). We found no differences in the rate of adverse events or lymphoedema over 12 months.

[*Julie Bruce et al. / Health Technol. Assess. 2022 Feb;26(15):1-124.*]

(a) What type of epidemiologic study design was employed by the investigators? *(3 Marks)*

(b) What do the authors mean by "*intent-to-treat analyses.*"? *(3 Marks)*

(c) What do the authors mean by "*complier-average causal effect analyses.*"? *(3 Marks)*

(d) Although loss to follow-up was not described in the abstract, it is possible that it took place in this study. Outline three possible measures you would take to reduce loss to follow up if you were invited to participate as an investigator in such a study. *(6 Marks)*

(e) The investigators might have chosen to recruit women aged ≥ 18 years who had been diagnosed with breast cancer and then measure their upper limb function using the Disabilities of Arm, Hand and Shoulder questionnaire as they determined through a questionnaire if the women engaged in regular exercise or not. What study design would this be and why? *(4 Marks)*

(f) Outline the advantages and disadvantages which might have arisen if the study design ((e) above) was used. *(6 Marks)*

2) The table below shows the results of a case-control study done in Igembe Central Sub-County in Meru to see if consumption of *Miraa*/Khat *(Catha edulis)* among youth aged 18 – 35 years was associated with dental caries (exposure status was determined using a self-administered questionnaire and the outcome status was ascertained by a study dentist):

	Dental Caries	
Miraa Consumption	Yes	No
Yes	141	113
No	185	515

An epidemiology Masters student was interested in this study and found out that some blood and urine samples had been taken and stored for possible future analysis. After examining the urine samples for presence of cathinone (the principal active component in *miraa*) she found that 20% of the youth (both cases and controls) who had reported no consumption of *miraa* had positive urine samples for cathinone. She thus made a new table correctly classifying the students using their new exposure status.

(a) Calculate the crude odds ratio for the initial study and state in clear terms the relationship between consumption of *miraa* and dental caries (*show your work*) *(5 Marks)*

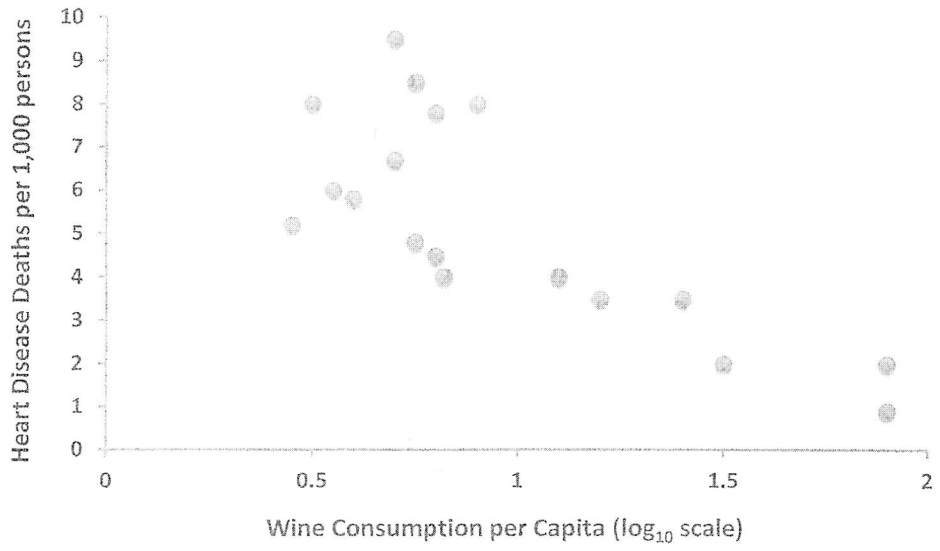
(b) Make a 2x2 table showing the new exposure status for the cases and controls (*show your work*) *(7 Marks)*

(c) Calculate the crude odds ratio for the new Masters student's analysis and state in clear terms the relationship between consumption of *miraa* and dental caries. *(5 Marks)*

(d) What type of misclassification was there in the initial study and what effect did this misclassification have on the odds ratio? *(3 Marks)*

(e) How would you ensure that such misclassification does not occur in a similar future study? *(5 Marks)*

3) An ecological study was done in 18 developed countries which showed an inverse correlation between the level of wine consumption in these countries and ischaemic heart disease deaths (i.e. the higher the consumption of wine the lower the ischaemic heart disease deaths as shown in the graph below). *[NB/ each dot represents a country]*.



(a) What features make this an ecological study? *(5 Marks)*

(b) Would you agree that being "sober" in these countries was a risk for death due to ischaemic heart disease? Why? Or why not? *(6 Marks)*

(c) If an individual level study was done (e.g. case-control study) in these countries and results showed higher ischaemic heart disease death rates in alcoholics compared to non-alcoholics what would be plausible reason/s for this? *(6 Marks)*

(d) Briefly describe how such a study ((c) above) might be carried out. *(8 Marks)*

4) Male circumcision has been shown to reduce the spread of HIV and other sexually transmitted diseases. It is however not known if male circumcision could reduce the spread of Chlamydia infection which causes pelvic inflammatory disease (PID) in women. Your mentor decides to carry out a study for 5 years to answer this research question.

(a) Briefly outline a study plan to address this research question with a prospective cohort study. *(10 Marks)*

(b) An alternative plan would be to compare the circumcision status of male-partners of women with pelvic inflammatory disease with those of women without PID. Compared with this "case control" approach, briefly outline the advantages and the disadvantages of your prospective cohort study. *(6 Marks)*

(c) Could the cohort study be designed as a retrospective cohort study and how would this affect your advantages and disadvantages? *(4 Marks)*

(d) Outline five (5) possible confounding factors in this cohort study and for each outline a reason as to why you think they are strong confounders. *(5 Marks)*

5) Read the following abstract and answer the questions that follow:

Introduction: Gestational diabetes (GDM) is a common complication, whose incidence is growing globally. There is a pressing need to obtain more data on GDM in low- and middle-income countries, especially amongst high-risk populations, as most of the data on GDM comes from high-income countries. With the growing awareness of the role HIV plays in the progression of noncommunicable diseases and the disproportionate HIV burden African countries like Kenya face, investigating the potential role HIV plays in increasing dysglycemia amongst pregnant women with HIV is an important area of study.
Methods: The STRiDE study is one of the largest ever conducted studies of GDM in Kenya. This study enrolled pregnant women aged between 16 and 50 who were receiving care from public and private sector facilities in Eldoret, Kenya. Within this study, women received venous testing for glycosylated haemoglobin (HbA1c) and fasting glucose between 8- and 20-week gestational age. At their 24-32-week visit, they received a venous 75 g oral glucose tolerance test (OGTT). Because of the pressing need to assess the burden of GDM within the population of pregnant women with HIV, a study was done where pregnant women with HIV within the larger STRiDE cohort were matched to non-HIV-infected women within the STRiDE cohort at a 1:3 ratio based on body mass index, parity, family history of GDM, gestational age, and family history of hypertension. The measurements of glucose from the initial visit (fasting glucose and HbA1c) and follow-up visit (OGTT) were compared between the two groups of HIV+ cases and matched HIV- controls.
Results: A total of 83 pregnant women with HIV were well matched to 249 non-HIV-infected women from the STRiDE cohort with marital status being the only characteristic that was statistically significantly different between the two groups. Statistically significant differences were not observed in the proportion of women who developed GDM, the fasting glucose values, the HbA1c, or OGTT measurements between the two groups.
Discussion: Significant associations were not seen between the different measures of glycaemic status between pregnant women with and without HIV. While significant differences were not seen in this cohort, additional investigation is needed to better describe the association of dysglycemia with HIV, especially in Kenyan populations with a higher prevalence of GDM.
[*Sonak D Pastakia et al. / Journal of Diabetes Research Volume 2021, Article ID 8830048.*]

(a) What study design was employed in this study? *(3 Marks)*

(b) The study does not indicate how the 249 non-HIV infected women were selected. Outline three (3) ways in which these 249 women could be selected. *(9 Marks)*

(a) What do you think the authors intended by matching HIV-infected and non-infected women in a 1:3 ratio in this study? *(3 Marks)*

(b) What were the main predictor and outcome variables in this study? *(4 Marks)*

(c) Was this study designed correctly? Why or Why not? *(6 Marks)*

6) Your epidemiology lecturer conducts a retrospective cohort study to assess whether elderly drivers (age ≥70) had poorer outcomes compared to younger drivers after being involved in road traffic accidents (RTA). Your colleague is very interested in the outcomes on this study so she requests your lecturer for the data. She stratifies the results using the variable "seatbelt" (which indicates if the driver was wearing a seatbelt or not at the time of the accident). The results are summarized below:

Seatbelt

	Died	Lived
Age ≥70	11	89
Age <70	24	1056

No Seatbelt

	Died	Lived
Age ≥70	13	37
Age <70	20	750

(a) Calculate the crude risk ratio and the two stratum-specific risk ratios. Show your calculations. *(9 Marks)*

(b) Based upon these calculations, would you conclude that the "seatbelt" is a confounder in the relationship between age of driver and RTA deaths? Why or why not? *(4 Marks)*

(c) Would you conclude that the "seatbelt" is an effect modifier in the relationship between age of driver and RTA deaths? Why or why not? *(4 Marks)*

(d) What other two factors might confound the association between being an elderly driver and the risk of death after a road traffic accident? *(4Marks)*

(e) How would you deal with these potential confounders ((d) above) when analysing the data from your lecturer? *(4 Marks)*