UNIVERSITY of York

The Department of Health Sciences

ASSESSMENT GUIDELINE

Module Title	Randomised Controlled Trials		
Module Code	HEA00159M	Module Level*	7
Word Limit /Exam Duration	2,500 words	Assessment Type(s)	Protocol/Case Report

Marking Criteria

Guidelines should be read in conjunction with the marking criteria guidance for the module level* noted above:
http://www.york.ac.uk/healthsciences/student-intranet/exam-assess/markgrid/

Confidentiality

It is a breach of confidentiality to disclose any personal information about a patient, service user, colleague, staff or any other person or place that could in principle enable them to be identified. For further guidance please refer to the departmental policy on Confidentiality at the following link: www.york.ac.uk/healthsciences/student-intranet/exam-assess/conduct/confidentiality/

Assessment Timing

The deadline for correctly presenting a submission is 4.30pm on the published submission date.
The submission deadline is published on the Programme Assessment Schedule available on the following link:
http://www.york.ac.uk/healthsciences/student-intranet/timetables/assessment-schedules/

Referencing

You **must** reference your work in accordance with departmental referencing guidelines which you can access via the following link:
http://www.york.ac.uk/integrity/harvard.html

Assessment Guidance

Students are required to design an original randomised control trial, write up a trial protocol and provide accompanying study documentation.

Formative assessment

Students will be asked to write bullet points or notes relating to the design of a RCT (500 words). They will receive qualitative feedback in terms of whether or not the key points of design were included or where items need to be further addressed in the main assignment.

Throughout the module formative exercises will be utilised to give students some practice in carrying out practical activities required to conduct a randomised controlled trial, and to provide them with the relevant feedback. However, there is no contribution to the mark for the module.

Summative assessment

Project (100% weighting to module mark)

Purpose of the Assessment: To assess the ability of students to design a randomised controlled trial, considering key elements as detailed in the task.

Assessment Task: This assessment requires you to design the following documentation for a randomised controlled trial.

1. Trial Protocol (1500 words)
   The trial protocol can be of any intervention in health. But it must be feasible and ethical.

2. Using the trial protocol develop the following study documentation:
   i) Participant Information Sheet Sections
      - What are the possible benefits of taking part? What are the possible disadvantages of taking part? (300 words)

   ii) A page of a Case Report Form to collect data on: patient demographics, condition history, primary outcome

   iii) Trial Application Sections:

- Summary of Main Issues - *Please summarise the main ethical, legal, confidentiality or management issues arising from your study and explain how you have addressed them*. (450 words)
- In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public? - *Give details of involvement, or if none please justify the absence of involvement.* (250 words)

To pass the student must:
Write a clear assignment following a logical structure in all documents. The assessment must be for a randomised controlled trial. Using the SPIRIT and Health Research Authority guidance will help the structure.

To get a good mark the student must:
<u>Protocol</u>

- Demonstrate an appreciation of why a trial is needed and justify the choice of design
- Justify and calculate a sample size calculation
- Address and appreciate potential biases

Use of complicated designs correctly will be awarded a higher mark; however a high mark can still be achieved if a simple design is well described and justified.

<u>Study documentation</u>
Demonstrate an appreciation of key elements to consider when designing patient facing documentation and to address and appreciate potential ethical concerns in relation to the trial.

Date last reviewed: July 2024 Reviewer: Catherine Arundel	Date last updated: July 2024	Date last reviewed by External Examiner: