Online participation

by SALLY BATHAM

Online participation submission for ITCT course

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University of Edinburgh 2013/14 Semester 1

MSc CT Introduction to Clinical Trials

Edinburgh University Semester 1 (2013/14)

Online participation assignment template

Note to course participant:

- If possible please use the table below for ease of marking the self-assessment part of the assignment. The table is expandable.
- Remember to save this template as a new file once you begin editing-include your UUN number in the filename/NOT your name.
- If you are submitting more than one posting per criteria please clearly number and date (date of posting) each one separately-use of a smaller font (8/9pt) is fine for the copy-pasted postings.

Part I. Self-assessment

Criteria	Unit origin of post (s)	Your selected posts (font 8/9 pt fine) inserted here (~1200 W in total)	Marks & self-assessment (75-100 W each)
Timeliness Postings are well written and usually made in a timely fashion (ie, in good time for others to read and respond to before the discussion closes).	Unit One/ Question 1 7/10/2013	A randomised controlled trial is a study where a number of similar participants are assigned to a certain group to test a specific drug or treatment. One group receives the drug or treatment or there may be several groups receiving different dosing regimens, another group may be allocated a placebo or no treatment at all. .Outcomes are measured at several time points dependent on the study protocol, responses from the different groups are analyzed statically. Randomised controlled trials have been particularly useful in the vaccine type studies I have been involved in especially when evaluating different doses to evoke a serological response in age stratified groups. The intention of these studies is to reduce bias.	8/10 I feel I have attained 8/10 as I have always been prompt in posting my replies. For example the unit 1 post selected was responded to on the day of the questions being posted, This prompted some further discussion demonstrated in the second post in response to Ben which would not have been possible

	Unit One Question 1 9/10/2013	Hi Ben One that immediately springs to mind is cost effectiveness, due to limited resources and an aging population resistance to adopting expensive treatments is always a barrier to implementation.	if the response to the initially question had been posted later in the week. I believe I have always been prompt and have not posted anything at the last minute. Unit 2 22/10/13, Unit 3 8/11/13, Unit 4 21/11/13 are examples.
			Mark out of 10:
Engagement Postings draw on other course participants' responses in a constructive way (ie, not simply confirming a similarity or difference in views, but elaborating and explaining similarities or differences.)	Unit 2 Question 3 4/11/2014 Unit 2 Question 3 30/10/2013	In terms of the PK sampling I am not sure you would get many people to take part as you point out this would be an intense, invasive procedure which would also come with cost implications and a relatively short overview of compliance. Measuring hypertensive drug levels in the blood as far as I know is not feasible. I do know of a situation locally, where patients on multi therapies to control blood pressure were still presenting with high readings, so noncompliance was suspected. The clinical team decided to invite these patients to a directly observed therapy session. Whereby they were observed taking their medication then their blood pressure was recorded at regular intervals. Interestingly a couple of them at such severe hypotension they needed admitting to hospital, clearly they had not been taking their medication, perhaps in their case it was a good thing! Thanks for pointing out Ben that the majority of us had opted to include all patients when most of them were probably compliant.	7/10 I have given myself 7/10 as I feel the two postings demonstrate that I have engaged with my fellow participants and responded in a constructive way to suggestions and ideas. I have responded on a number of occasions to my peers and tutors. However I acknowledge that I lacked the foresight in not directing any questions or comments directly to the tutors and hopefully this is something I can improve on in future discussion forums.
			Mark out of 10:
Relevance Postings are relevant to the general themes of the Thought questions.	Unit 2 Question 3 29/10/2013	In answer to the question posed the target group would be those who are on medication for hypertension and attend the hypertension clinic. The study design could either be a cohort or randomised control trial. In the RCT half the cohort could be randomised to receive feedback session with the nurse and the control group randomised not to receive the intervention. You could measure the primary outcome by comparing the 2 group's blood pressure readings over a period of time and drawing a conclusion from the results. A secondary outcome could be a quality of life assessment (euroquol). Another avenue to explore as suggested by Glasziou et al would be gathering data through	7/10 I have given myself 7/10 because I feel that this post demonstrates the relevance to the general theme and the question being asked in unit 2. The study design for hypertensive noncompliant patients in a clinic. The thoughts and ideas I had around the design of a trial were put forward in order to address the

		qualitative research on the reasons why patients did not take their medications correctly this could then be quantified. My only other thought is why the consultant had arrived at this conclusion in the first place was it due to patients presenting with abnormally high blood pressure readings or could there be some other reason such as drug modification, not because they were not adhering to the treatment. May be this would warrant further exploration.	question posed. Relevant comments were also posted towards the end of the thread in order to provoke further discussion which had relevance to the topic and to the engagement criteria above.
I			**Mark out of 10:**
Critical thinking Postings demonstrate evidence of critical analysis and exploration of concepts and ideas relevant to the general themes of the Thought questions, or other themes that have emerged in the discussion.	Unit 4 Question 3 25/11/2013	Having reviewed the material regarding recruitment, I think there are several elements which can affect recruitment rates. Recruitment can be dependent on the complexity of the study EG: Number of visits, tests, inclusion exclusion criteria, duration and the disease being studied maybe rare. Questionnaire studies can be easier to recruit two especially if the patients are seen at their routine clinic appointment reducing the need for any extra visits to the hospital where car parking can be an issue. Getting the research message across to the general public and dispelling myths is also a challenging one. I agree with Lesley Breen that self-benefit is a motivator for taking part in a trial and the Dundee website was the most visually pleasing, easy to navigate and focused on studies. The others seemed to incorporate a lot more information which I feel distracted from the main focus. I agree with Tze Shin that social media will have a larger to part to play in the future but could exclude those who don't have access. I live in Leicester which is a large multi-cultural city so language can be a barrier unless the information is translated or interpreters are available however this can be costly. In the past when we have struggled to reach the recruitment target for a study and we had tried all the usual routes, posters , letters etc..... we have visited various local groups which have included church coffee mornings and the WI in an attempt to boost recruitment. This worked to a degree but I haven't come across a recruitment strategy yet which has been totally successful.	6/10 I have given myself 6/10 because I think the posts do provide some evidence of critical thinking, drawing upon the material presented in Units 1 and 4, my responses and my own personal experience. I have also put forward some ideas and practical points relevant to the question asked. However I always find it difficult to critically analyse concepts. My score reflects the need for further development in this skill.
	Unit 1 Question 4 18/10/2013	Blinding can also be difficult in Influenza vaccine trials, when you are using adjuvant and non adjuvant vaccine. One is a clear solution and the other cloudy, so the only way it can be blinded is to ask the participant to look away while administering the vaccine. So one could argue whether this is truly blinded or just an attempt to blind in a rather crude way	

			Mark out of 10:
Evidence base Where relevant, key points in postings are supported by good use of current literature, from the Unit readings and elsewhere.	Unit 2 Question 1 22/10/2013	Although the research question shapes the study type or design as Roehrig et al suggests there are other practical issues to consider if the study is to have any value, reliability or to stand up to regulatory scrutiny. Being on the practical side of clinical trials I am always amazed by the over predication of some clinicians to how many subjects are potentially available to take part in a clinical trial and the practical pitfalls this brings, regarding statical power etc.....The study design should also be sensible, factoring in numerous long unmanageable visits can deter potential participants and effect the follow up phase. So the study design need to be feasible taking into consideration the finance, resource and staffing implications. Conducting the trial will as highlighted in Duley and Farrell not be achieved without communication and collaboration with the key players. Another important point to make is the randomisation system should be robust to limit bias and prevent clinicians from influencing the treatment participants receive. So my first five steps before setting up a trial would be: Practical, feasible, collaborative, robust randomisation and statical power	7/10 I have awarded myself 7/10 as I feel I have demonstrated in the three examples from units 1,2 and 3 the use of recommended unit reading and I have drawn upon the literature in composing my answers to the questions posed. This has enabled me to explore the key points made by the authors to further expand my knowledge and inform my practice EG: The importance of collaboration with key players and having a charismatic leader to improve the success of a trial.
	Unit 1 Question 2 9/10/2013	I don't agree with Gaw and Burns that good communication between stakeholders and researchers is the only barrier to implimentation. Has Greenhaigh points out in chapter 1, limited budgets and resources can lead to the cheapest option without regard for effectiveness. However with consumers having access to the internet the demand for sophisticated novel treatments will put pressure on economic costs.	
	Unit 3 Question 1 8/11/2014	Having read the Bandolier paper I think the conclusions drawn are that: Statistical significance can be generated by chance, so random chance cannot be ignored. The Meta analysis described in the Bandolier paper of smaller trials draws me to the conclusion that smaller trials are more prone to chance effects than those with larger cohorts.	

	As Duley and Villar suggest the need for larger randomised controlled trials reduces random error and allows for a more reliable effect of the intervention. My opinion regarding the need for single or multiple trials to influence practice is dependent on the size of the trial whether it is multi centre so to generate enough statistical significance , the area of study and that the literature supports the notion that larger trials do generate more reliable results. However this can be a challenge when studying rare but serious conditions such as studies on patients with Huntingdon Disease which we are currently involved in. .		
TOTAL MARKS		Mark out of 50:	35

Part II. Reflections

Having missed the two weeks preparation I felt at a disadvantage in terms of getting to grips with the technology and finding my way round Moodle and the discussion boards. I thought the questions and themes explored generated some interesting and thought provoking discussion. It was particularly interesting to hear the views of those in other parts of the world and getting a different perceptive on the issues raised and discussed, it gave us all the opportunity to relate discussions to our own experience and practice.

In unit I, I engaged in the discussions around the randomised controlled trial and how it should reduce bias (discussed in question 4 posts 14/10/2013 and 18/10/2013), and the barriers around implementing findings into clinical practice. This prompted my response regarding cost effectiveness because of the constant challenge in my area of work regarding the cost of HIV medication. Most agreed with Torgerson the RCT being the gold standard, threads highlighted the barriers and limitations, which I referred to in my post 11/10/2013. This theme also continued in the history lesson thread. Greenhaigh points out limited resources can be a barrier, whilst Gaw and Burns indicated good communication was essential, whilst I don't disagree these are essential the consensus was that other factors need to be considered when designing trials.

After my unit 2 question1 posting regarding the first five steps, and reading others responses and suggestions were mine too simplistic. It was certainly highlighted in the reading Roehrig, Duley and Farrell that other steps need to be considered before embarking on a study. I really enjoyed engaging in the hypertension clinic scenario as I was able draw from my own practice and offer advice to my peers.

Unit 3 was a challenge, although I do see the necessity to be able to interpret the results of trials. The partner reading such as the Bandolier paper and the Dudley and Villar comments that large trials are needed to reduce error helped me gain an understanding of the concepts discussed. The idea of stratified medicine the video (Prof Cameron) was certainly a new concept to me and I noted with interest the comments by others regarding difficulties with implementation especially in other countries.

The final unit was the one I could fully engage with as this relates to my practice. Although I recognise my naivety when discussing comparator bias this was certainly a revelation to me and calls into question current regulations. The recruitment debate I can fully concur with on a practical level this is the one single issue which to my mind hinders the success of a clinical trial. However listening to Lesley Breen, reviewing the three different recruitment strategies and the 'singing professor', this has certainly given me some recruitment ideas to pursue.

Participating in the discussion boards has enabled me to engage with other professionals in the field of clinical trials and has highlighted areas of further learning and development such as getting to grips with statistics. The support from my peers around the discussions has been excellent with many including myself relating to areas within our own clinical practice and suggesting further reading. This activity has highlighted the need to critically develop knowledge due to the ever changing regulations around the conduct of clinical trials.

Online participation

GRADEMARK REPORT

FINAL GRADE

55/100

GENERAL COMMENTS

Instructor

Dear course participant,

Thank you for your assignment submission. Please find below the tutor's marks and comments as laid out in the assignment specifications folder for the Online participation assignment Parts I & II:

Part I:
Timeliness
Agreed, and you have provided evidence beyond the compulsory post in support of your assessment. 9/10 pts

Engagement
Agreed. This is an informative and thoughtful post underpinned by research prompted directly by a response to a tutor. 8/10 pts

Relevance
Agreed. Your post is clearly aligned to the topic at hand and you draw from relevant readings but in order to explore further try to make links to your own personal experience, your own professional practice as well. 7/10 pts

Critical thinking
Agreed. You evaluate and explore ideas, which you extend in part even further by comparing to your local setting and the implications of the differences there on recruitment rates which is very good as you are presenting different perspectives. For deeper levels of critical thinking try drawing also from the literature in support of/or against ideas presented, ask yourself what else might lie at the root of recruitment success that has not been mentioned, challenge an idea brought forth, consider alternative conclusions that could be drawn.....7/10 pts

Evidence base
Agreed. You have drawn from the course readings and but you could demonstrate your competence even more by making links to results from external literature and current practice which should be referenced fully. 7/10 pts

Total tutor mark: 38/50 pts
Participant mark: 35/50 pts
Average: 36.5/50 pts

Part II
Section 1: Descriptive account of new experience but not on how this new experience made you feel initially and how/if this feeling changed over time. As this was a new communication experience were there any initial questions this raised about online learning/communicating in general? Was it easy/hard/daunting/tedious to logon? To scroll through reems of posts? etc. Your refer to 'us' but this is the space to reflect on 'you'! 5/10 pts

Section 2: You describe selected examples of your online learning but you do not expand further on the online discussion experience itself and how your feelings/approach to a new form of communications changed as the weeks/Units went on. Was there anything that surprised/angered/scared you about the online discussion? 15/30 pts

Section 3: A bit more evidence of reflective thinking than previously. You share the consequences the experience had for your own professional development and practice, for example. It would have been helpful further, to be more specific about how the online discussions supplemented the formal Unit lessons-or not ? What would you do differently the next time based on this experience? 6/10 pts

Total Tutor mark:26/50 pts
+ Part I average: 36.5/50 pts

Final mark: 62.5/100 pts (B)

This is a very good result!

The Tutor Team

General note about reflection:

On the MSc CT we regard reflection as the opportunity to learn from the learning experience itself (here participating in online discussions) rather than from the learning material. In addition to the valid points you have already made when reflecting in the future try asking yourself even more about

the (here) discussion experience - for example, what is familiar/unfamiliar compared to other forms of communication? How have your feelings changed about the online discussion experience compared to the very first post? How has this impacted on your learning-if at all? What are the questions your experience raises about your approach to learning/communicating in general? Is there anything you would do differently the next time?

PAGE 1

PAGE 2

PAGE 3

PAGE 4

PAGE 5

PAGE 6

PAGE 7

PAGE 8