Online Participation and Reflection

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MSc CT Introduction to Clinical Trials

Online participation submission for ITCT course

S1366428

University of Edinburgh 2013/14 Semester 1

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	Unit 1, Thought Question 3, posted Thursday 10 October 2013, 11:09am Supporting Timeliness	Hypothesis: Can reducing cholesterol in otherwise healthy individuals reduce the risk of ischaemic heart disease? This was the first clinical trial I participated in as a research nurse, many years ago. The West of Scotland Coronary Prevention study (WOSCOPS) recruited 6,595 middle aged men with elevated LDL cholesterol and no history of myocardial infarction (MI) to this randomised double blind trial, participants received either pravastatin or placebo over a 5 year period. The results demonstrated a significant reduction ($p<0.001$) in cardiovascular events. A 10 year follow up using the national computerised record linkage system concluded that 5 years treatment with pravastatin was associated with a significant reduction in coronary events for a subsequent 10 years in men with hypercholesterolemia who did not have an MI. Earlier research had demonstrated treatment with statins had some effect for patients post MI, the results of the WOSCOPS study changed prescribing habits as statins are now used as preventative measure. The UK was the first country globally to have statins available without a prescription (2004) Source Long-term impact on healthcare resource utilization of statin treatment, and its cost effectiveness in the primary **prevention** of	I have awarded myself 9/10 for timeliness as my responses to the relevant questions are posted in a timely manner with adequate opportunity for responses from my peers. On all but one occasion where the post required a description of a clinical trial I ensured all posts were <250 words to make sure peers had time to read the post and consider responses. On two occasions I posted the first comments, this was a challenge for me as I have never engaged in group discussion at this level and was anxious others may find my thoughts not relevant

		cardiovascular disease: a record linkage **study**.	
	Unit 2 Thought Question 4 Posted Monday 21 October 2013 11:16pm Supporting Timeliness	A randomised, crossover, double blind comparison of the analgesic effect and patient tolerability of nabilone and dihydrocodeine in chronic neuropathic pain, BMJ. 2008 January 26; 336(7637): 199–201.Published online 2008 January 8 This study randomised 96 adult subjects from three UK sites with a diagnosis of chronic neuropathic pain and a mean pain score of ≥ 40mm on the 0-100mm visual analogue scale. Randomisation was stratified by centre using permuted blocks of 10 to begin treatment with nabilone or dihydrocodeine. The per subject study duration was 14 weeks (6 week treatment 1, 2 week washout period followed by 6 week treatment 2) Both trial drugs were administered in a titrated manner, dose reductions due to adverse effects was permitted. The primary endpoint was effect on pain, in order to eliminate bias from carryover effects the pain scores for the last two weeks of each treatment period (week 4 or week 12) was analysed. Although the author reported a superior analgesic effect with dihydrocodeine it is not clear if the analysis is based on differences between the two groups rather than individuals. I believe the rationale for choosing the crossover design for this study was to demonstrate that the expensive nabilone is not different to dihydrocodeine in terms of pain and the secondary objectives including tolerability, antidepressant and anxiety reducing. As this condition is chronic and the effect of the intervention temporary a crossover design may seem reasonable, however the weakness in crossover design for this study was the large number of drop outs, this may have led to a within-subject comparison impossible. As the study medication was titrated the results do not provide information of the dose tolerated by the subjects. With the hindsight of reviewing the results of the study I think a parallel group design may have provided more substantial results.	
			Mark out of 10:9/10
	Unit 4		I have awarded myself 7/10 as

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.)	Thought Question 2 Posted Sunday 24 November 2013, 3:36 pm Supporting Engagement. Unit1Thought Question 4 supporting Engagement	I think the issue is lack of provision of information to the IRB/IEC and investigators. If there is any doubt comparator bias does occur bodies like the APBI should be working with the regulatory bodies to ensure the protection of clinical trial participants and society, which is the basic principle of GCP/ICH. Arguing that comparator bias does not exist because REC approves the studies and doctors conduct the trials is deficient. A meta-analysis could be included in the study protocol. This would empower the IRB/IEC and the investigators I had thought subversion bias to be almost obsolete with IXRS and IVRS! I have witnessed situation where the subject has either consciously or by chance unblinded themselves to the study drug, on both occasions by having blood test performed out with the clinical trial facility and providing the researcher with the results. One study in diabetes and one hypercholesterolemia.	although I have met the criteria demonstrated in the selected posts by raising a view which resulted in a discussion with my peers, In general I have answered the question rather than encouraging responses from my peers'. It is as a result of this exercise that I realise my focus has been to answer the questions rather than actively engage in a group discussion. My focus was to use the thought Question to demonstrate my comprehension of the materials or information we had been provided with during the course unit.
			Mark out of 10:7/10
Relevance Your posts relate directly to the general themes of the thought discussion as prompted by the questions and/or subsequent	Unit 2 Thought Question 1 Posted Monday 28th October, 3:08pm Supporting Relevance	My thoughts are: I am assuming I have a question with a need for an answer. I. How many subjects will I need to recruit and for how long in order to answer this question and any additional secondary endpoints, for example how many "events" do I need. II. Where will I find the subjects (primary/secondary care) and how will I recruit the sites/investigators?	I have awarded myself 8/10 as my posts are relevant to, and prompted by the question asked. I based my response on relevant materials studied during the appropriate unit. I viewed the Thought Question as an opportunity to "stop and think" did I understand the materials presented and the key points, was I able to make logical

discussion		III. Assuming I have the intervention what will I as use a comparator/control? Consider if placebo is ethical for this study, what other similar interventions (if appropriate) are available. Will the comparator affect the number of subjects needed or duration of the trial? IV. What is the potential harm to the subjects and can this minimized without compromising the study outcome? V. How will I monitor the progress to ensure the trial is on track? Contingency plan may be required for example amendment or early termination.	connections between the various sources of information, videos, recommended reading, journals etc and apply that understanding to the question.
			Mark out of 10:8/10
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 2 Thought Question 4 Posted Monday 21 October 2013 11:16pm Supporting Critical Thinking	A randomised, crossover, double blind comparison of the analgesic effect and patient tolerability of nabilone and dihydrocodeine in chronic neuropathic pain, BMJ. 2008 January 26; 336(7637): 199–201.Published online 2008 January 8 This study randomised 96 adult subjects from three UK sites with a diagnosis of chronic neuropathic pain and a mean pain score of ≥ 40mm on the 0-100mm visual analogue scale. Randomisation was stratified by centre using permuted blocks of 10 to begin treatment with nabilone or dihydrocodeine. The per subject study duration was 14 weeks (6 week treatment 1, 2 week washout period followed by 6 week treatment 2) Both trial drugs were administered in a titrated manner, dose reductions due to adverse effects was permitted. The primary endpoint was effect on pain, in order to eliminate bias from carryover effects the pain scores for the last two weeks of each treatment period (week 4 or week 12) was analysed. Although the author reported a superior analgesic effect with dihydrocodeine it is not clear if the analysis is based on differences between the two groups rather than individuals. I believe the rationale for choosing the crossover design for this study was to demonstrate that the expensive nabilone is not different to dihydrocodeine in terms of pain and the secondary objectives including tolerability, antidepressant and anxiety	I have awarded myself 8/10. Drawing from the materials provided in unit 1 and 2 I performed a critical analysis of this study and explored the concept of the importance of selecting the appropriate study design and analysing potential weakness in a study results due to inappropriate study design selection. As evidenced in the examples of the posts I presented they are based my general thoughts of the question with specific attention to relevant training materials and learning objectives provided for the unit.

		reducing. As this condition is chronic and the effect of the intervention temporary a crossover design may seem reasonable, however the weakness in crossover design for this study was the large number of drop outs, this may have led to a within-subject comparison impossible. As the study medication was titrated the results do not provide information of the dose tolerated by the subjects. With the hindsight of reviewing the results of the study I think a parallel group design may have provided more substantial results.	
Evidence base Where relevant, key points in postings are supported by good use of current literature, from the Unit readings and elsewhere.	Unit 1, Thought Question 3 posted Thursday 10 October 2013, 11:09am supporting Evidence base	Hypothesis: Can reducing cholesterol in otherwise healthy individuals reduce the risk of ischaemic heart disease? This was the first clinical trial I participated in as a research nurse, many years ago. The West of Scotland Coronary Prevention study (WOSCOPS) recruited 6,595 middle aged men with elevated LDL cholesterol and no history of myocardial infarction (MI) to this randomised double blind trial, participants received either pravastatin or placebo over a 5 year period. The results demonstrated a significant reduction ($p<0.001$) in cardiovascular events. A 10 year follow up using the national computerised record linkage system concluded that 5 years treatment with pravastatin was associated with a significant reduction in coronary events for a subsequent 10 years in men with hypercholesterolemia who did not have an MI. Earlier research had demonstrated treatment with statins had some effect for patients post MI, the results of the WOSCOPS study changed prescribing habits as statins are now used as preventative measure. The UK was the first country globally to have statins available without a prescription (2004) Source Long-term impact on healthcare resource utilization of statin treatment, and its cost effectiveness in the primary **prevention** of	**Mark out of 10:8/10** I am awarding 7/10 for the evidence based criteria. I have demonstrated from this post relevant use of supporting documents to provide a comprehensive answer to the question. In general my responses to the unit thought questions are formulated on course learning materials, relevant journals, textbooks or my personal experience. I realise now I should be providing source information in support of my answer or response, rather assume others have access to the same materials. This course is the only formal education I have engaged in for more than 20 years; the 3 months have proved to be a positive learning curve.

	cardiovascular disease: a record linkage **study**. McConnachie A, Walker A, Robertson M, Marchbank L, Peacock J, Packard CJ, Cobbe SM, Ford I. Eur **Heart** J. 2013 Jul 9.	7/10
TOTAL MARKS		Mark out of 50:39/50

Part II. Reflections

I consider myself to be a confident adult and enjoy active discussion. I was not at all fazed with the concept of the group thought discussions, it therefore took me quite by surprise when I was presented with the first opportunity to contribute and I felt quite anxious about what my peers would think about my posts, was I as experienced as the others? Would my thoughts be considered irrelevant? Did I really have anything to offer? I found it quite a daunting prospect and admit to having to summon up some courage to participate.

Unit 1, the thought Question 3 considered the hypothesis of a study; I decided I needed to dive in and posted a response from experience of a study I had enjoyed working on. Over the course of the unit a discussion ensued in relation to early termination of clinical trials due a positive benefit. One of the participants asked if it was always a good thing to stop a trial early due to clear benefits. This was of great interest to me, I hadn't considered that there may be adverse effects of early termination; I considered it unethical to continue the trial. I read some literature including a paper recommended by a course participant (noted below) and found myself thinking on a

new level. I did not however have the confidence at that time to provide my own personal thoughts. Unit 2 Thought Question 4 asked for examples of different types of trial design, then consider the rationale for the choice of study design and describes it briefly to the group. I was particularly interested in n-of-1 clinical trials introduced to the unit, I had never heard of this trial design before. Despite reading the literature and understanding the concept of the design I could not find any n-of-1 trails registered on the UK Clinical trials gateway or controlled-trials.com. I concluded I needed to work on my competence at searching and selected a different study design for my post. I then learned from others they had attempted to search the registers and also failed to find an n-of-1 study registered. This gave me a wakeup call, I must not be afraid of my findings, if they don't provide me the results I expected I will take that to the group and open a debate, I was sorry I opted for the safe choice.

In summary, I soon learned that the Thought Questions are not, as I initially and shamefully considered them to be another "task" rather than the positive experience they have proven to be. The forum offers a fantastic opportunity to draw for the experience of the other participants, which is a huge invaluable resource. There is no doubt as demonstrated in the previous paragraph I have learned a great deal, however in terms of personal development I have learned the value and the potential to increase my knowledge base by engaging with my peers rather than being concerned about exposing a weakness.

Problems of Stopping Trials Early, BMJ 2012;344:e3863vdoi:10.1136/bmj.e3863 (Published 15 June 2012)Early Termination of Clinical Trials May Overestimate Treatment Effects, Laurie Barclay, MD, March 23, 2010n-of 1 clinical trial: The ultimate strategy for individualizing medicine, Elizabeth O Lillie

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GRADEMARK REPORT

FINAL GRADE

84/100

GENERAL COMMENTS

Instructor

Dear Karen,

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

Part I:
Timeliness
Agreed, by posting early and adhering to the word limit you have helped facilitate engagement and discourse by others. 9/10 pts

Engagement
Agreed. This is an informed post clearly underpinned by readings, but try responding directly to your peers' posts and highlighting this. By doing so you can play a key role in collaborative knowledge construction. 7/10 pts

Relevance
Agreed. Your post is clearly aligned to the topic, which you have activley engaged with by asking probing questions. 8/10 pts

Critical thinking
Agreed, but only for the second half of the post. You have assessed and analysed the status quo and explored another option, but you did not provide a rationale or evidence for either. By underpinning your ideas with evidence from the literature or even your own experience your argument becomes stronger as it is informed-and not 'just an idea'. 5/10 pts

Evidence base
Agreed. You have drawn from a limited range of course readings and mention results from the literature and current practice. 7/10 pts

Total tutor mark: 36/50 pts
Participant mark: 39/50 pts

Average: 37.5/50 pts

Part II
Section 1: Honest personal account of new experience including how your anxiety surprised you and the questions this raised about your own competency. 10/10 pts

Section 2: You describe selected examples of learning taking place including the experience itself and what the implications of the experience were on the manner in which you participated in the discussions. Clearly learning about the issue of stopping a trial early from others, for example helped you revisit your own view-and which you have reflected upon 28/30 pts

Section 3: Again there is strong evidence of reflection as demonstrated in the implications of your online discussion experience for your own personal development. Something else to think about at this point is how the online discussions supplemented the formal Unit lessons/or not? 9/10 pts

Total Tutor mark:47/50 pts
+ Part I average: 37.5/50 pts

Final mark: 84.5/100 pts (Highest mark in class)

This is an excellent result-you already are a reflective practitioner who has recognised reflection as the opportunity to learn from the learning experience (here participating in online discussions). Well done!

The MSC CT Tutor Team

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