Use of an virtual clinical trial lab curriculum increases student understanding of the scientific method and communication

Abstract

In contrast to traditional expository approaches to biochemistry laboratory teaching, many novel alternatives have emerged in recent years. One approach is to incorporate simulated “real world” tasks into the lab experience, such as research-related activities, that are frequently engaged in by the scientific community. In this study, we designed and implemented a virtual clinical trial comparing the effects of high-protein and low-fat diets on metabolic outcomes into a second year Biochemistry & Metabolism course, which we hypothesized would increase student understanding of elements of scientific communication and the scientific method. The secondary research objectives of this study were to assess if the change in understanding was related to student learning approach and academic performance. Students (n=39) completed the Revised Two-Factor Study Process Questionnaire 2 (R-SPQ-2F), and a survey assessing understanding of scientific method/communication before and after implementation of the laboratory curriculum. Improvements in student reported understanding of scientific communication and methodology were significantly improved upon completion of the lab activities; no relationships were observed between learning approach or grade and the average mean change in understanding. As the focus shifts away from traditional instruction towards alternative approaches, virtual clinical trial curricula may effectively improve the learning environment of the biochemistry laboratory, although these results should be interpreted with consideration of the uncontrolled design of the study.

Key Words

Biochemistry, laboratory, simulated research environment, undergraduate education, pedagogy

Introduction

The paradigm shift in contemporary postsecondary education has moved from “providing instruction” to “producing learning” (Fisher 2011). Following this, it has been a priority in post-secondary biochemistry classrooms to assess student laboratory learning experiences. Science laboratory activities are learning experiences where students have the opportunity to interact with materials to observe and understand the natural world (Hofstein and Lunetta 2004). Remaining consistent over the past 80 years, the goals of biochemistry laboratory instruction are to i) reinforce concepts from lecture; ii) improve laboratory skills; iii) promote positive attitudes towards science; iv) convey scientific processes; and v) learn facts about the nature of chemistry (Elliott, Stewart and Lagowski 2008). Traditionally, biochemistry laboratories have been conducted in an expository manner. Expository instruction reinforces concepts from lecture-based instruction. Approaches are highly focused with little room for students to pursue concepts of their own (Elliott 2006). A major limitation of expository instruction is that students can successfully complete laboratory exercises with very little understanding of relevant chemistry concepts (Powell 2010, Garratt 1997, Garratt 2002, Hunter, Wardell and Wilkins 2000). Following a prescribed protocol represents only a small aspect of the entire process of experimental science (Hunter, Wardell and Wilkins 2000). Laboratory work is often over-emphasized at the expense of planning the investigations and interpreting results (Garratt 2002). Students are primarily concerned with getting a good result and therefore a good mark; they
often fail to fit the laboratory experience into their existing knowledge on the topic (Garratt 1997). Research has demonstrated that the expository, “cookbook” laboratory approach allows students to successfully complete exercises; however, students do not necessarily understand the critical scientific concepts tied to the activities (Powell 2010). Hein (1991, emphasis added) provides insight into this challenge, noting that “all hands-on activities must also pass the test of being minds-on; they must provide something to think about as well as something to touch”.

In contrast to expository instruction, problem-based laboratory methods promote a more “minds-on” approach to learning. Within the realm of problem-based instruction lie many alternative approaches to teaching biochemistry, including simulated research environments, the goal of which is to promote critical thinking and to engage students by allowing them to experience chemistry in a more applied way (Powell 2010). The process of justifying assertions about the natural world using data collected within or beyond the science classroom is considered an increasingly important aspect of science education (Hofstein and Lunetta 2004). Land and Zembal-Saul (2003) found that when learners were prompted to articulate and connect their experimental findings back to the larger driving questions, they negotiated and struggled with explaining the significance of the data. This struggle motivated students to explain and justify their findings, often through reflective discussions with peers (Land and Zembal-Saul 2003). Thus, as students engage in activities that reflect the work of real scientists, they have the opportunity to make connections and develop scientific critical thinking skills. Specifically, simulated research environments give students the opportunity to understand the scientific method. The scientific method is one of the five categories in which students have major misconceptions (Egger 2009). Gelbart, Brill, and Yarden (2009) report that simulated research environments “may contribute to the contextualized understanding of how scientific knowledge is created and evaluated”. Therefore, a major misconception held by science students may be better understood through participation in simulated research environments.

Considerable learning potential lies in the randomized controlled trial (RCT) research environment. In the RCT study design, subjects are grouped into either a treatment or control group; after a set period of time, the treatment group can be compared to the group receiving no treatment to determine the effect of the intervention. In order to accurately design the study and interpret results, RCTs must uphold high standards of scientific communication and methodology. Key scientific concepts of RCTs include randomization, eligibility criteria, blindness, and cause and effect. For groups to be scientifically valid in their comparisons, they must be as alike as possible, and the best way to achieve this is through the process of randomization (Stanley 2007). This avoids bias and ensures that each subject has equal chance of receiving the treatment under study. Second, eligibility criteria are defined as “the key standards that people who want to participate in a clinical study must meet or the characteristics that they must have” (US National Institutes of Health 2012). Eligibility criteria are comprised of inclusion criteria, the factors that allow a person to participate in an RCT, and exclusion criteria, the factors that prevent a person from participating in an RCT (US National Institutes of Health 2012). The appropriate eligibility criteria must be outlined so as not to bias or confound the results of a study. Third, blinding is commonly used to prevent bias in RCTs. Different types of RCTs exist based on the groups that are blinded; the appropriate blinding design must be chosen for a given study (US National Institutes of Health 2012). Finally, RCTs are a powerful demonstration of cause and effect. They are the most effective method of determining whether a cause and effect relationship exists between an intervention and a pre-defined outcome
Research Questions

In this study, a directed type of problem-based laboratory curriculum was developed in which students were provided with specific activities and data and were responsible for the analysis and interpretation of the data. This laboratory curriculum was a clinical trial research simulation that covered aspects of scientific communication and the scientific method. The following research questions were investigated:

1. Does a virtual clinical trial laboratory curriculum in undergraduate biochemistry increase understanding of elements of scientific communication and the scientific method?

2. Is the change in understanding related to student learning approach and final course grade?

Methods

Participants

Subjects were enrolled in Biochemistry & Metabolism II at the University of Guelph Humber in Fall 2012. Assessment of students consisted of two tests and a final exam as well as several in-class assignments (such as concept maps) and lab activities throughout the semester. All students in the class (n=64) were invited to complete a questionnaire regarding their understanding of scientific communication and the scientific method. The questionnaire was completed on two occasions, once at the beginning of the semester (week 1, in the first laboratory class) and a second time at the end of the semester (week 11, in the last laboratory class). A total of 39 students gave informed consent and responded to both questionnaires. This study received clearance from the Research Ethics Board at the University of Guelph.

Procedures

a) Laboratory curriculum

Prior to the start of the course, individual subject data sets were created. Each subject file included baseline 3-day diet records, as well as records for the subject on high protein and low fat diets. Blood test results were created for each diet with measures of blood lipids, inflammation, and glycemic control. Appetite ratings and anthropometric data were also provided. Laboratory activities occurred weekly throughout the semester for 1 hour and 45 minutes per session, worth 25% of each student’s final grade in the class. Skills and concepts over the course of the laboratory curriculum are presented in Table 1. The progression of the virtual clinical trial simulation is outlined in Figure 1.

Table 1: Skills and concepts targeted for each week of the KIN 2070 laboratory. Consistent across each week is presenting research findings in a written primary research report.
<table>
<thead>
<tr>
<th>Week</th>
<th>Skills and Concepts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Informed consent, randomization, eligibility criteria, study design</td>
</tr>
<tr>
<td>2</td>
<td>Types of scientific publications and content of primary research articles</td>
</tr>
<tr>
<td>3</td>
<td>Data input and concept of baseline measurements</td>
</tr>
<tr>
<td>4-5</td>
<td>Research methodology</td>
</tr>
<tr>
<td>6</td>
<td>Data input and concept of measurement changes across time</td>
</tr>
<tr>
<td>7</td>
<td>Data compilation</td>
</tr>
<tr>
<td>8-10</td>
<td>Data analysis and presentation of data, including statistics, figures and tables</td>
</tr>
</tbody>
</table>

**Figure 1: KIN 2070 Laboratory Curriculum Development and Process**

**b) Laboratory surveys**

Students completed the Revised Two-Factor Study Process Questionnaire 2 (R-SPQ-2F), which is designed to measure whether students take a deep or surface approach to learning. Initially created as the Study Process Questionnaire, this revised version consists of 20 questions, with 10 items representing each approach, and it has four subscales that describe motive and strategy (Biggs, Kember and Leung 2001). The R-SPQ-2F has recently been shown to best describe the two factors of deep and surface as measured by their 10 corresponding items (Justicia et al. 2008), so these are the variables that will be considered in this investigation.

Students also completed a questionnaire regarding their perceived understanding of clinical trials, scientific communication and the scientific method. For each statement, students indicated their perceived level of understanding using a scale of 1 through 10, where 1 is no
understanding and 10 is complete understanding. Table 2 lists the questions in the laboratory questionnaire. Each student completed the survey twice, as described above. By comparing the scores from both time points (hereafter referred to as the mean pre-lab score and mean post-lab score), the students’ changes in understanding could be assessed. Only the questionnaires of students who gave informed consent were used in this investigation. A total of 39 out of 64 students participated in the study.

Table 2: Laboratory Survey Questions (answered using a scale of 1-10, where 1 is the lowest level of understanding and 10 is maximal understanding)

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Mean Pre-Lab Value (± SEM)</th>
<th>Mean Post-Lab Value (± SEM)</th>
<th>Mean Change (± SEM)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel that I understand how to design a clinical trial.</td>
<td>4.18 (0.326)</td>
<td>6.90 (0.289)</td>
<td>2.718 (0.435)</td>
<td>&lt;0.0005*</td>
</tr>
</tbody>
</table>

(i)  Statistics

All data was analyzed using IBM SPSS version 20 and the P value was set at less than 0.05. Paired T-tests were performed to determine the relationships between mean pre-lab score and mean post-lab score of each question in the laboratory survey. Linear regression was conducted to determine the association between i) mean change in overall understanding and deep approach score, ii) mean change in overall understanding and surface approach score, and iii) mean change in overall understanding and final course grade. The assumption of normality was as assessed by the Shapiro-Wilk test.

Results

(i)  Pre-post differences

Paired T-tests were conducted to determine whether there was a statistically significant mean difference between post-lab scores and pre-lab scores in the laboratory survey. Table 3 describes the mean pre-lab values, mean post-lab values, and the mean change with associated p value. All observations showed significant increases in ratings of understanding from pre- to post-measurement.

Table 3: Survey scores before and after the biochemistry laboratory experience.
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Mean (SD) 1</th>
<th>Mean (SD) 2</th>
<th>Mean (SD) 3</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>I feel that I understand how to run a clinical trial.</td>
<td>4.21 (0.319)</td>
<td>6.72 (0.284)</td>
<td>2.513 (0.397)</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>3</td>
<td>I feel that I understand how to randomize subjects in a clinical trial.</td>
<td>4.87 (0.377)</td>
<td>7.18 (0.299)</td>
<td>2.316 (0.403)</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>4</td>
<td>I feel that I understand how to include and exclude subjects in a clinical trial.</td>
<td>4.77 (0.351)</td>
<td>7.31 (0.273)</td>
<td>2.538 (0.404)</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>5</td>
<td>I feel that I understand what to include in the introduction section of the paper.</td>
<td>5.77 (0.344)</td>
<td>7.46 (0.307)</td>
<td>1.692 (0.369)</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>6</td>
<td>I feel that I understand what to include in the methods section of the paper.</td>
<td>6.61 (0.334)</td>
<td>8.00 (0.244)</td>
<td>1.395 (0.323)</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>7</td>
<td>I feel that I understand how to present written results in a research paper.</td>
<td>6.03 (0.334)</td>
<td>7.74 (0.289)</td>
<td>1.718 (0.433)</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>8</td>
<td>I feel that I understand how to present data figures in a research paper.</td>
<td>6.15 (0.311)</td>
<td>7.41 (0.302)</td>
<td>1.256 (0.367)</td>
<td>0.001*</td>
</tr>
<tr>
<td>9</td>
<td>I feel that I understand what to include in the discussion section of a research paper.</td>
<td>6.21 (0.297)</td>
<td>7.62 (0.276)</td>
<td>1.410 (0.356)</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>10</td>
<td>I feel that I understand how to interpret findings in a research paper.</td>
<td>5.97 (0.286)</td>
<td>7.21 (0.236)</td>
<td>1.231 (0.299)</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>11</td>
<td>I feel that I understand how to write a research report.</td>
<td>5.77 (0.299)</td>
<td>7.51 (0.243)</td>
<td>1.744 (0.305)</td>
<td>&lt;0.0005*</td>
</tr>
</tbody>
</table>

* indicates significance, p<0.05

(ii) **Associations with learning approach**

There were no significant associations for mean change in understanding with either surface or deep learning approach, as presented in figures 2 and 3.
Figure 2: Scatterplot depicting the relationship between mean change and deep learning approach score ($R^2\text{ linear}=0.012$, $p=0.071$). Trend line is represented by the following formula: mean change $= 3.196 - (0.060 \times$ deep approach score).

Figure 3: Scatterplot depicting the relationship between mean change and surface learning approach score ($R^2\text{ linear}=0.037$, $p=0.748$). Trend line is represented by the following formula: mean change $= 1.970 - (0.011 \times$ surface approach score).
(iii) **Associations with grade**

There was no significant association between mean change in understanding and final grade, as presented in figure 4.

![Figure 4: Scatterplot depicting the relationship between mean change and final grade (R^2 linear=0.015, p=0.726). Trend line is represented by the following formula: mean change = 0.823 + (0.012 x final grade).](image)

**Discussion**

The objective of this study was to determine if a virtual clinical trial research simulation increased understanding of elements of scientific communication and the scientific method, and if the changes in understanding were related to student learning approach and course grade. It was determined that student understanding of all measured aspects of scientific communication and methodology significantly improved; a direct relationship was also observed between deep learning approach and the average mean change in understanding, although the relationship did not quite reach significance. Therefore, the results of the present study demonstrate that the virtual clinical trial experience is a valuable laboratory curriculum for undergraduate biochemistry students.

The primary objective of this study was to determine whether participation in a virtual clinical trial research simulation could effectively increase student understanding of components of the scientific process and communication. The post-lab surveys showed highly significant increases in understanding across all questions (p<0.001 for all questions). Students indicated improved understanding of how to design and run a clinical trial, randomize subjects, and create
appropriate inclusion/exclusion criteria. Students also showed improved understanding of how to write a primary research paper, including writing the introduction and methods, appropriately presenting results, and interpreting and discussing the findings. These findings support the notion that students who engage in simulated research activities develop “contextualized understanding” of scientific knowledge, learning how it is created and evaluated (Gelbert, Brill and Yarden 2009). The virtual clinical trial experience in the present study supported previous findings of the positive impact of simulated research environments; student understanding improved along the entire continuum of research, from the study design, to data collection and analysis, to interpreting and communicating scientific results.

A secondary objective of this study was to determine if the change in understanding over the course of the virtual clinical trial was related to student learning approaches and final grade. Neither learning approach nor final grade was significantly associated with change in understanding. These findings are somewhat surprising. Our hypothesis was that surface learning approach would be inversely correlated, and deep learning approach directly correlated, with an increase in understanding. Our hypotheses were based on the known characteristics of deep and surface learners, with deep learners actively seeking to understand why phenomena occur (Biggs, Kember and Leung 2001), and surface learners tending to approach learning with rote memorization and getting the task done with minimum time, effort and personal commitment (Biggs, Kember and Leung 2001). Therefore, we expected that deep learners, with their drive towards understanding material, would show greater gains in understanding of the scientific method and scientific communication across the semester, while surface learners would show lesser gains. We similarly anticipated that student final course grade would be directly correlated with an increase in understanding, as we expected that greater understanding of the scientific method and communication would result in improved performance on course assignments and exams, which were in part dependent on competency in these areas. Our lack of observed associations between gains in understanding and learning approach and final grade may in part be attributed to the highly significant changes observed by the majority of students, which would limit our ability to detect subtle differences between students as related to individual characteristics. As well, this study is limited by its small sample size (as described below), which would hinder our ability to observe associations with small effect sizes.

The primary limitation of this study is the uncontrolled nature of the study design, as there was no control group that participated in a more traditional biochemistry lab curriculum, which clearly limits the conclusions that can be drawn regarding cause and effect. As well, it is uncertain whether the changes seen across the semester were related to participation in the virtual clinical trial lab or to some other concurrent learning experience, although it is known that students were not simultaneously taking courses in research design or methodology. This study is further limited by the small sample size, as although the class consisted of 64 students, only 39 students wrote both pre- and post-lab questionnaires and gave informed consent. Future work in this area should assess one or more larger group of students (for example, in the same course comparing a virtual clinical trial lab to a different lab component, or in the same course with no lab component) in order to draw more reliable conclusions.

Two considerations of the implementation of the virtual clinical trial lab curriculum presented in this paper are the initial investment of time to create mock subject data, and the potential need for modification depending on the course schedule. Forty-six mock subject files
were created for the present curriculum, each requiring 3-day diet records, and anthropometric and biochemical data for both baseline and intervention diets, which required an approximately two-month preparation period. As well, the curriculum presented in this paper is designed to run in a weekly laboratory format, although it could be modified to fit into a tutorial or even implemented as a class assignment. Thus, ample preparation time must be factored in for the development of virtual clinical trial curricula, and modifications to adapt to the specific lecture, lab, and/or tutorial components of the course may be necessary.

The results of the virtual clinical trial research simulation support findings that the use of nutrition in biochemistry teaching has a positive impact. For example, Heidemann & Urquhart (2008) used an assignment to determine if claims made on energy drinks were accurate to increase student engagement, while Pogozelski et al. (2005) observed a vast improvement in classroom engagement and enthusiasm when they discussed a nutrition application in their biochemistry course. Passos and colleagues [28] used a very similar teaching strategy to the current study, in which students in a basic biochemistry course observed differences in blood biochemistry of subjects on a high carbohydrate diet compared to a high fat diet. However, the experiment by Passos et al. (2006) required volunteer student subjects and blood analysis. The use of a research simulation, as in our study, avoids the added costs, complexities and risks associated with a real experiment, while preserving the benefits of problem-based learning and student engagement. Thus, the results of the virtual clinical trial laboratory described in the present study add to the growing body of evidence supporting the role of nutrition in improving biochemistry teaching.

Conclusion

Prior research has determined the effectiveness of incorporating simulated research environments into biochemistry teaching. In this study, a virtual clinical trial laboratory curriculum was developed. Students were provided with specific activities and data and were responsible for the analysis and interpretation of the data. The objective was to determine if the virtual clinical trial simulation increased understanding of elements of scientific communication and the scientific method, and if the changes in understanding were related to student learning approach and course grade. Student understanding of RCT design and implementation was significantly improved upon completion of the virtual clinical trial. In addition, students reported significantly greater understanding of how to write a research paper, from the introduction and methods sections, to presenting, interpreting and discussing results, although these results should be interpreted with consideration of the uncontrolled design of the study. As the focus shifts away from traditional instruction towards alternative approaches, virtual clinical trial curricula may effectively improve the learning environment of the biochemistry laboratory.

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