

L7 - Research Methods and Professional Development (ACFA7004)

MSc Project Proposal:

The Development and use of a Web Application
to aid Clinician Involvement and Patient Agency
in Clinical Trial Recruitment

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1. Research Introduction and Background

The working title for the proposed research is:

The development and use of a web application to aid clinician involvement and patient agency in clinical trial recruitment

Clinical Trials (CTs, also referred to as “trials” hereafter) are crucial to advancing medicine and finding new treatments. Research indicates a shortage in trial enrolment, and that many patients are not aware of trials appropriate for them. Recruitment is the largest cause of trial delays [1]. This proposed research intends to develop a web application to improve patient awareness, knowledge, and enrolment in Urology CTs in Swansea Bay University Health Board (SBUHB). Usability testing with non-patients, and unstructured interviews/demonstrations will provide qualitative and quantitative data. This data will highlight the application’s usefulness to both patients and clinicians.

Agency, particularly patient agency, is a crucial focus of this research. Human agency is defined as: [2], [3, p. 347]:

“The capacity possessed by people to act of their own volition ... all agency arises from and is relative to the options made available by a person’s position in a wider culture, society, economy, and political system”

In this project’s context, patient agency refers to patients’ ability to make decisions and control their health care [4].

1.1. Background and Hypothesis

The concept of this project originated from a SBUHB research concept to develop a web application to aid patient agency through access to CT information. The intent is to increase Swansea Urology patient enrolment in CTs, particularly cancer trials.

Further to an approach from a SBUHB Urology surgeon, initial needs and expectations were established. The need for increased trial enrolment was emphasised, which was due to a range of barriers to patient enrolment (further explored in the literature review). Initial ideas concerning the web application were discussed, such as enabling staff to add, edit, view, and delete trial records. A patient search functionality was an expectation, which would link patients to trials managed by staff, based on patients’ individual conditions.

The focus is to empower patients, encouraging patient-led trial recruitment. As such, any developed interface should be accessible and comprehensible. Also discussed was the lack of uniformity in trial data across Wales, resulting in clinicians’ lack of awareness of available trials. This resulted in a lack of uniformity in patient screening for eligibility, which was also determined as a feature of the application.

From this background, the following hypothesis has been defined:

Can the use of software systems increase both awareness and involvement of clinicians, and agency in patients with Urological conditions in Swansea, who are searching for clinical trials?

1.2. Research Aim and Objectives

The research aim and its five objectives outline the goals of the project, and are detailed below:

Aim:

To develop a web application to support clinicians and aid patients in finding CTs which are supported by their hospital, and to determine whether it can improve patient agency.

Objectives:

- Review current literature, developing understanding of both barriers to CT participation and proposed solutions
- Determine requirements of staff and patient users through unstructured interviews with clinicians
- Design user interfaces and a database to facilitate requirements
- Develop a web application which implements feature requirements
- Evaluate the developed system to test the hypothesis, accomplished via:
 - o Usability testing of the application with non-patients
 - o Unstructured interviews with clinicians

1.3. Outcomes and Deliverables

This research will provide two deliverables. Firstly, a web application will be developed to facilitate clinician and patient access to trial information. This will facilitate the second deliverable - research data. This data will determine the feasibility and usefulness of the application, along with its use in testing the hypothesis.

The web application will be split into patient and clinician portals. The clinician portal will facilitate management of trial data, while the patient portal will allow patients to search for trials applicable to them. The application will consist of both front-end and back-end code, and a database storing trial information.

The data will consist of both quantitative and qualitative data, concerning the current problem and requirements, along with evaluation of the application. This evaluation will determine whether such a system can increase clinician involvement, patient agency and trial enrolment, thus testing the hypothesis.

1.4. Scope and Limitations

Given the computing perspective of this research, it does not aim to determine or alleviate clinical issues involved in CT enrolment. In particular, the literature review will focus on only technical and accessibility concerns for CT enrolment. Regarding application development, for example, a system will be developed allowing patients to check if they meet eligibility criteria. The underlying clinical issues surrounding eligibility criteria stringency and other medical topics are outside the scope of this project. Furthermore, much of the background research focuses software applications developed for clinicians, rather than patients. This is a limitation due to a dearth of prior research in the field. However, it has also identified an area that would benefit from further research. There is little contemporary research reviewing patient enrolment barriers. Some barriers may have changed since the publishing of these papers, given the increased availability of technology and information.

Due to potential ethical and access concerns, data collection and evaluation will not involve patients. This is the primary limitation of this work, as evaluation and data collection will be primarily through non-patients. Therefore, the research will test if the application can improve patient agency when searching for trials, but would not test if it could increase enrolment in a realistic scenario. While this provides valuable research data, it does not incorporate patients, thus not being entirely representative of the intended users. Clinician involvement includes Patient and Public Involvement (PPI) forum staff, SBUHB Urologists, and NHS Wales Health Collaborative.

The timeframe for this project is limited, however there is potential to continue this project in further research. This limitation would primarily affect data gathering and evaluation.

1.5. Section Conclusion

This section has introduced the proposed research, a hypothesis, an aim, and its respective objectives. Deliverables and scope have been identified, and key definitions provided. The next section conducts a preliminary review of literature surrounding CT enrolment barriers and tools.

2. Literature Review

The review or related work consists of two distinct areas. The first relates to research conducted about the problem – CT accessibility, awareness, and barriers to enrolment. These related works focus on identifying barriers and their extent, not on addressing them. Secondly, papers which propose or develop solutions to trial enrolment, and more broadly, patient agency, are reviewed. As described in the project scope, this review does not consider clinical barriers, instead focusing on information, accessibility, and technical barriers.

2.1. Barriers to CT Enrolment

This subsection investigates barriers to trial enrolment, considering the effects on clinicians and patients. The full literature review will further detail barriers to younger patients, and clinician difficulties.

There are a wide range of barriers to CT enrolment. Many barriers are strictly clinical, and as such are outside the scope of this project. Three primary barriers to CT enrolment were identified. Firstly, patients have little awareness of CTs which are available to them. Often, patients have no way to find relevant trials. Secondly, clinicians are also unaware of many CTs, thus making them unable to advise their patients of them. Finally, of the CT matching or searching sites, few are aimed at the patient. The target audience of many of these sites is clinical staff involved in patient care and trial recruitment. As such, most of the information and language in these sites is not accessible to patients, often requiring advanced medical knowledge to understand.

Mills et al. [5] conducted a review of 33 studies on barriers to trial participation. They determined the most common barrier to trial enrolment, excluding clinical reasons, to be patients' poor awareness of trial opportunities. Also discussed was the complexity and stringency of the enrolment conditions, along with the terminology used, which dissuades potentially eligible candidates. The authors propose that providing more educational information to patients would alleviate these issues. Little consideration was given to the approach of adapting information to be patient-accessible, which would alleviate the necessity to provide patients with additional information/education.

More recently, Wong et al. [6] shared these findings. they determine three major barriers found through oncologist interviews. The primary non-clinical barrier was limited access to resources, affecting both staff and patients. Example resources were listed, primarily educational materials including handouts and websites. Their research also found lack of trial awareness to be an issue. However, unlike the previous paper, this barrier was only found to be present in clinical staff, such as oncologists. Though not explicitly stated as a patient barrier, it is to be expected that patients would also be unaware of CTs if the staff who care for them are not aware. The primary barrier to patients was their negative beliefs or attitudes towards medical research. If patient awareness was increased using a platform to present trial information in accessible language, patient attitudes towards CTs could significantly improve. Their paper gathered information on both patient and clinician barriers. However, patient barriers

were discerned through interviews with oncologists, not with patients. Therefore, although their findings are in line with other research, interviewing patients as opposed to clinicians could provide more insight.

In 2006, Agrawal et al. [7] found that in long-term oncology patients (with cancer for a mean of 4.8 years), a reported 10% mortality rate in a trial would not prevent many of these patients from enrolling. Despite this, they determined that the majority of these patients do not understand the trial's purpose or have sufficient information about it. This issue remains prevalent today. ClinicalTrials.gov, a major database of clinical studies around the world, was recently evaluated by Stergiopoulos et al. [8] and Gof et al. [9]. Both studies shared findings, in particular that using the website from a patient's perspective would not yield full or accurate results. Gof et al. determined that site-specific contact information was unavailable for more than 40% of entries, hindering patients' agency. They suggest that an interface upgrade is warranted, to improve patients' opportunities of finding trials.

Simon and Hegedus [10] selected 66 CT websites they found through internet searches for "cancer clinical trial", and evaluated their content and quality. They noted that many could be useful to patients and clinical investigators, but that a large proportion were difficult to navigate and understand, some relying on scientific language. A 2008 Datamonitor Consulting report [11] shared these findings. It evaluated four major CT websites, with mixed results. Some were found to have extensive information, while not being user-friendly due to interface and language concerns. Others were accessible and readable but provided little detail and no contact information. Monaco and Drills [12] discuss in further detail reading levels of trial websites. 39 National Cancer Institute Comprehensive Cancer Centre (NCI CCC) websites were evaluated, finding that most trial descriptions were written at university reading level. They acknowledged the necessity of some medical language, but suggested trial information be presented more accessibly. One major acknowledged limitation of the study was the lack of inter-rater reliability. Despite this, their findings appear accurate, as they agree with previously reviewed papers from the same period.

2.1.1. Older Patients in CTs

Technological barriers and trial awareness have been shown to be more prominent in older patients. Sedrak et al., a prominent author in the field, used semi-structured interviews to determine medical oncologist's views of trial enrolment in older cancer patients [13]. Patient awareness and understanding were identified as significant barriers. Community oncologists identified these barriers more frequently than academic oncologists (45% vs 10%). Comparable to Wong et al.'s approach, this paper is also limited in that it ascertained patient barriers through discussion with oncologists, not patients. This approach also identified oncologist time as a limitation, given the time investment required to manage and enrol patients (identified by 11% of oncologists). Both academic and community oncologists shared the view that lack of understanding of CTs impacts older patients more than younger ones, particularly regarding the expectation/concern of being "experimented on". The authors acknowledged the limitation that those oncologists interviewed were all within a single health network, with a limited sample of 44 oncologists. This finding regarding patients' expectations of medical research was found to be generalisable to many patients

regardless of age, by Unger et al. [14]. They investigated patient attitudes towards research and found that patients frequently reported feeling “uneasy” or “fearful” about the prospect of participating in medical research. It was determined that the research process must be further explained to patients. This could be facilitated through a web resource.

Sedrak et al. also conducted a systematic review of research papers [15]. This work shared findings of their previously discussed paper, along with finding transportation concerns, and perceived participation burden were prevalent, possibly linked to lack of understanding. Sedrak et al. conducted another review of 13 studies [16], highlighting that only 24% of US CT participants are above 70 years of age. As such, they are underrepresented. This work discussed in further detail older patients’ barriers to trials, citing emotional burden, patients believing they are “too old” for trials, and concerns of trial efficacy and drug toxicity. This finding is similar to that discussed by previous papers, though this provides additional details. Patient concerns of drug toxicity, trial eligibility, and belief that they are too old, form part of the overall concern of patient knowledge/awareness. A patient-focused information and recruitment website could alleviate these issues by providing understandable explanations, which are rarely included in generic recruitment sites. The paper provides recommendations to improve older adult inclusion and participation in medical research, though focuses only on clinical issues and patient feedback. The paper makes no suggestion for improved resources for patient access. It also supports the findings of Fearn et al. in 2010 [17]. Their work determined that older patients report altruistic reasons for trial participation, although also found that these patients did not fully understand trial information. It discusses the requirement for readily available, understandable trial information, and the importance of good communication with older patients about trials.

Liu et al. recently investigated strategies to improve older adult participation in trials, particularly recruitment barriers [18]. Their findings echo those of earlier studies, suggesting that despite the time difference, findings of older studies remain relevant. Their paper suggests further research should be conducted to determine older patients’ desires and needs from medical research, and to further integrate technology, primarily telehealth, into medical appointments and trial enrolment. They suggest telehealth is used to reduce the burden on patients and healthcare providers, by improving access to care and information. This was suggested despite low adoption of technology among older patients. This paper acknowledges the necessity for additional research into the feasibility, adoption, and sustainability of telehealth for CTs.

2.2. Resolutions to Enrolment Barriers and Patient Agency

This subsection explores approaches to mitigate enrolment barriers, and applications which aid clinician involvement and overall patient agency. The full literature review will further detail general patient agency applications and varying health board approaches from different countries. It will also explore other recruitment methods such as social media.

2.2.1. Generic Agency Applications

Various digital approaches can benefit patient agency. Hanna et al. created and evaluated a Personally Controlled Electronic Health Record (PCEHR) system for an Australian health service [19]. The system, named “Medenotes”, was evaluated through semi-structured interviews with 12 patients. This is a limited number, though this allowed more in-depth discussion with each patient. Relevant to this dissertation, the primary perceived advantage of PCEHRs was improved quality of care through improved patient-clinician communication. Another highlighted benefit was that all data was available from one source.

Hoogenbosch et al. further explored this, analysing use of a hospital patient portal [20]. 439 hospital patients completed a questionnaire about the portal. 32% indicated using the portal, 31% were aware of it but did not use it, and 37% were unaware of it. Chronic illness was associated with increased use of the patient portal. Surveys indicated that overall, portal users found it beneficial.

Marien et al. developed a medication reconciliation system to combat medication discrepancies and increase patient engagement [21], [22]. The system consisted of a patient application for reporting medication usage, and a clinician application to manage medication based on patients’ reporting. This application was well-received in its evaluation by 48 clinicians during usability testing – clinicians were its focus. Although deemed useful, the authors noted the necessity to increase interoperability between the two applications. Sardaneh et al. developed an electronic medication management system, also for the purpose of medication reconciliation [23]. The authors highlighted that clinicians recorded medication reconciliation in a more timely manner once using the system.

2.2.2. Software Applications for Trial Recruitment

In 2005, Metz et al. evaluated OncoLink, stated to be the oldest and one of the largest cancer information resources on the internet [24]. This site launched in 1994 and added patient trial matching in 2002. In a 15-month timespan, 627 eligible patients were found through the site, demonstrating its effectiveness. Online applications were approximately split equally between patients, and family on their behalf. This finding is relevant, as this dissertation aims to aid not only patients, but their family in finding trials. Importantly, this paper found that even in 2005, patients and family were willing to use the internet to find CTs and enrol on them.

In 2017, Mohs et al. detail the impact of a newly developed web-based recruitment application [25]. They found that this application benefitted trial recruitment, though only with considerable advertising. This finding is limited, as the authors state more data is required to determine the exact impact. Also noted was that use of site-specific trial databases was considered effective by 94% of documented sites. These findings were shared by Fenner et al. [26], who explored Facebook advertising for attracting patients to their trials website. They found that the combined cost of the website and advertising, comprising primarily of advertising, was US \$20 per eligible patient, deemed highly cost effective.

Toddenroth et al. implemented a CT recruitment monitoring dashboard for clinicians and trial investigators [27]. This locally deployed Electronic Data Capture (EDC) application was well-received by trial investigators and deemed extremely useful on the assumption that it can be modified to support automatic, daily updates. A more basic version of this functionality could be implemented for this dissertation, providing a monitoring and feedback element for clinicians. Authors noted their study was limited in that they did not ascertain feedback for individual features, only the overall application. Mattingly et al. developed a similar dashboard to aid researchers in managing trial enrolment [28]. In surveys of researchers and trial managers, 77% felt that the application made management and communication “easier” or “much easier”. However, this is limited as the study included only 23 staff.

Cohen et al. developed a trial matching website for breast cancer in 2012 [29]. 12 research sources contributed a total of 55 trials to the developed website. In the first 14 months, the site received 733 registrations from visitors, of which 407 matched to at least one trial. Surveys were sent to patients who completed the site’s health history check. Of the 20% who responded, 31% then contacted the research site. A total of 16% (52% of those who contacted a site) were found to be eligible. This resulted in 6% of patients who responded to the survey enrolling in a trial. This study was limited in that only those who completed the health history check were invited to discuss and disclose their eligibility and enrolment statuses. This does not represent those who did not provide health history information.

Brøgger-Mikkelsen et al. recently conducted a systematic review of research on online trial recruitment [1]. This study reviewed 61 papers, and found online recruitment through advertising or trial websites to be significantly more effective at finding and recruiting patients than offline methods. Also highlighted was the substantially lower cost per enrolled patient of online compared to traditional methods (US \$72 vs US \$199, with $P=0.04$).

2.3. Section Conclusion

This section has reviewed two areas of literature. Barriers have been explored, determining awareness, availability, and readability of resources to be problematic. Software applications have been explored, demonstrating their effectiveness in increasing patient agency and aiding clinicians in caring for patients. The next section conducts a methodological review of both research and development methods.

3. Methodological Review and Expected Results

This section describes and reviews the chosen methodologies and expected results. Resources and ethics are considered in relation to methodological approaches.

3.1. Research Philosophies and Approaches

This research will take a mixed methods approach, incorporating both positivistic and phenomenological approaches and strategies. This is due to the project's focus on people and their experiences [30]–[32]. Mixed methods, primarily through usability testing and unstructured interviews, will provide qualitative and quantitative benefits [33], [34]. Subjective, qualitative data will aid generalisability, while quantitative, precise data will increase reliability, supporting a primarily deductive approach and hypothesis [31].

3.2. Research Strategies

3.2.1. Literature Review

A preliminary literature review has been conducted, highlighting barriers to trial participation and patient agency tools. The dissertation will expand upon this work in both breadth and depth, as detailed in the preliminary literature review. This will inform other research strategies, especially development of a new application.

3.2.2. Software Development

Software development will entail design and implementation of a web application, along with a relational database. Given the widespread, highly accessible nature of websites compared to other types of application, this decision was straightforward. Server-side web development will use the PHP language and MySQL database server, due to their low footprint. This combination is an industry standard, part of the Linux, Apache, MySQL, PHP (LAMP) stack. Given the intent to regularly meet with a SBUHB clinician during development and review progress, the development will loosely take on an Agile approach. Features will be developed iteratively, and timeboxed between meetings, in a Scrum-like sprint approach.

3.2.3. Usability Testing

This work's primary source of data will be through usability and User Experience (UX) testing. UX focuses on understanding applications' users, their needs, expectations, abilities, and limitations [35], [36]. Usability, part of UX, is the extent to which a product can be used to achieve specific goals [37]. For web applications, this also encompasses web accessibility, the design and implementation of disability-friendly websites [38], [39].

Non-patients will be used as testers, as patients are not accessible. Participants will be adults found through a research call in the local area. Testers will be provided with patient details to adopt. These details will be used when searching for trials, allowing participants to emulate patients. The same set of patient details will be provided to each tester for result consistency. An example of these details is shown in Table 1. Trial data will be adapted from the ClinicalTrials.gov database. Testing will be conducted on personal devices due to social distancing limitations. This provides the benefit of testers using familiar devices. Additionally, this provides the benefit of a real-world scenario. A questionnaire will allow testers to evaluate the application. This questionnaire will include instructions and tasks to undertake. Participants will be asked to indicate whether they used a mobile or desktop device when evaluating the web application, as this may impact their experience. Phone support will be available to enable users to access the site and questionnaire, this will manage technical difficulties.

Table 1: Example UX patient details

Basic details	
Condition specialty:	Urology
Affected organ:	Prostate
Condition name:	Localised prostate cancer
Age:	43
Gender:	Male
City of residence:	Swansea
Additional information	
Have any other conditions?	No
Had any treatment?	Radiotherapy
Any medicine allergies?	Aspirin

UX testing will primarily involve participants using the application as it is expected patients would. Participants will not have the same motivation as patients; thus, usability data will not be identical to if it were tested with patients. However, it is expected that the findings of non-patient evaluation would be highly translatable and generalisable to patients, especially as they are more familiar with their condition than the general public. Such an approach would produce reliable data with 30 expected participants, with reasonable validity given aforementioned factors. The primary steps for testers in using and evaluating the proposed application are listed below:

- Find and use the trial search functionality, inputting relevant clinical details
- Navigate through trial results
- Find and comprehend eligibility criteria
- Contact clinical staff once a suitable trial is found

On completion of these steps, data will be generated for success rates at each step, providing quantitative data. The System Usability Scale (SUS) survey [40] will be used to provide highly valid and reliable quantitative data about qualitative issues within the sample group [41]. This scale consists of ten questions, with Likert-style answers. These are used to calculate a usability score from 0-100, where average usability applications score 68. Immediately after completing the tasks, participants will respond to the SUS, as recommended [40]. The SUS is effective at differentiating those who successfully used an application from those who experienced difficulty [42]. Finally, open-ended questions will be used to provide qualitative data.

Quantitative SUS data will be interpreted through graphical representation, and scores can be compared against known values. Analysis of qualitative data from open questions will be more complex and interpretative.

This methodology is limited by the current COVID-19 pandemic. Observation during testing will be limited due to social distancing, however, phone discussion will facilitate continuous feedback during testing. Ideally, eye tracking would be included, though this is more suitable for future work.

A preliminary version of the UX testing document is included in the Appendix.

3.2.4. Unstructured Interviews and Meetings

Unstructured interviews will be conducted throughout development, incorporated into the agile approach. These will provide clinician-level feedback and contextual information. On completion, the application will be demonstrated to SBUHB Urology clinicians and the NHS Wales Health Collaborative, to evaluate outcomes. These demonstrations will encourage feedback and evaluation from clinician and business perspectives. This data will be highly valid as clinicians are heavily involved in the CTs process, although individual clinician responses may vary, affecting reliability. Once data is interpreted, it will aid in testing the hypothesis and understanding views and motivations of clinicians [43], while providing modification suggestions for the application. Further details will be determined once development is complete.

3.3. Resources

Few technical resources will be required. A basic computer with the appropriate development environment installed is the extent of development resources. An Apache web server, along with PHP and MySQL installations will be required. The application will be stored locally in the development environment. The application may need to be hosted online for usability testing, incurring small costs, likely through cloud providers. This will depend on home network suitability. Microsoft Office will facilitate data collection, evaluation, and online video meetings.

Access to information resources will be required throughout the project. The university's online library is sufficient for literature sourcing. Clinical information and context will be provided by the clinical contacts collaborating on the project.

Usability testing participants and clinicians will be required to evaluate the application and test the hypothesis. Clinician input is readily available, while usability testing participants will be procured once development is completed.

3.4. Ethical Considerations

There are few ethical issues with the project, as it will not involve patients. All data will be collected anonymously. UX testers will be over 18 years of age. Actual trial data will be handled by clinicians, outside of this research. This will ensure that once the site is launched publicly (beyond the scope of this research), patients will not be misled by inaccurate trial information. As such, the website's trial content will be managed externally to this research.

3.5. Timeline

Work towards the dissertation officially begins around May, though much of the groundwork is undertaken earlier, through this proposal. Development will already be underway. This approach allows for data gathering and analysis to be prioritised during time allocated for the dissertation. A GANTT chart for the suggested project timeline is shown in Figure 1.

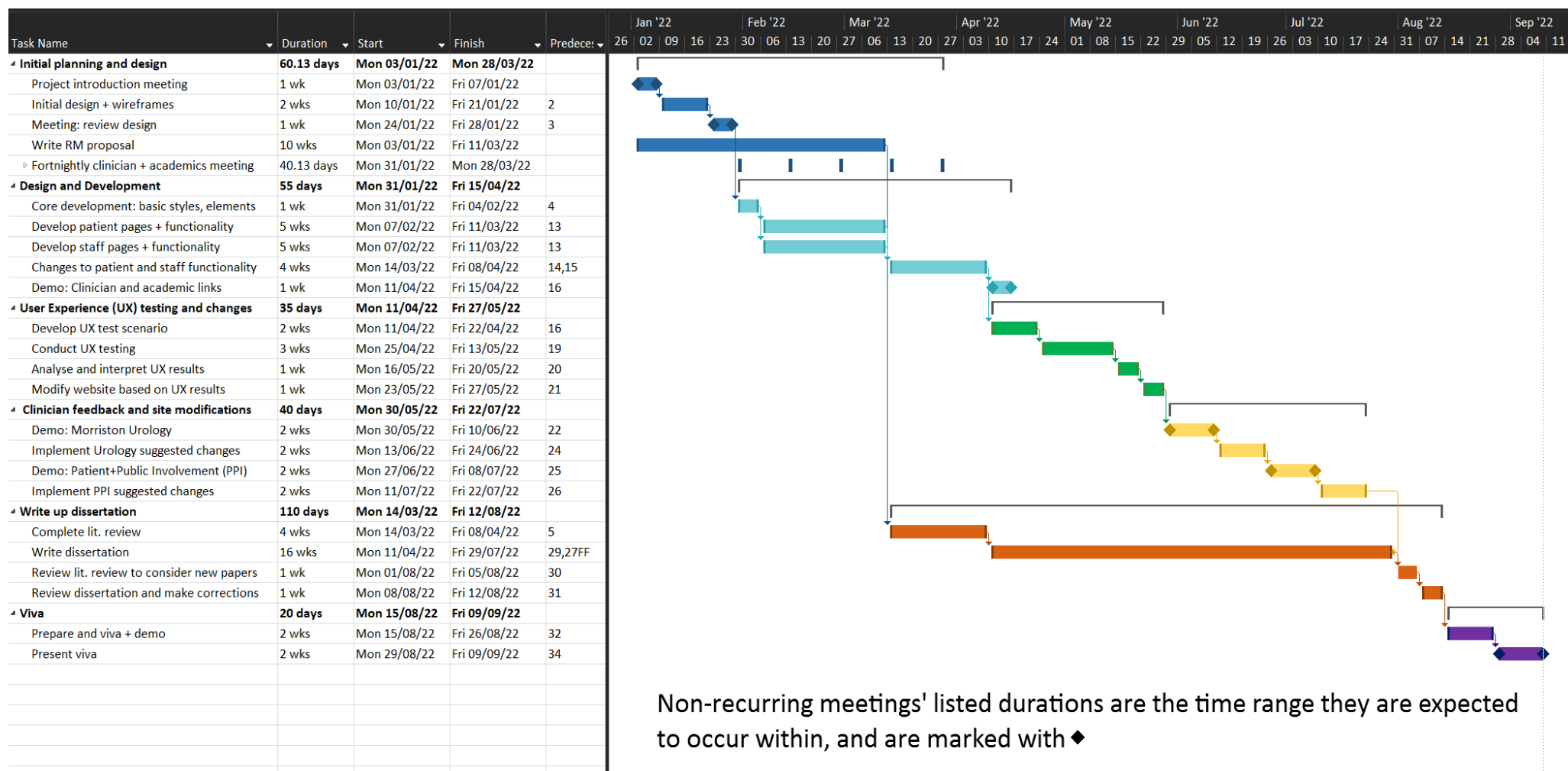


Figure 1: Project timeline

3.6. Risks

This work has both generic and project-specific risks associated with it. The primary risks specific to this project are clinicians withdrawing from qualitative feedback, and difficulty in acquiring UX testers. Clinician involvement will be closely monitored, while the project will be kept relevant to them. The project could continue without clinician feedback, though this would not be ideal. In the event of difficulty finding UX testers, university connections will be utilised to find participants. There is a small risk of funding withdrawal, though this is unlikely to affect the academic aspect of this work; it will only impact the commercial component. Some UX participants may find the medical context of the usability testing upsetting – a disclaimer will be provided at the start of any forms or instructions.

Generic risks to this project primarily consist of requirements inflation, overrunning the timeframe, and student or supervisor illness. Requirements will be closely reviewed with clinicians and the project supervisor. Additional requirements would affect the commercial aspect of the project, while academic work will be unaffected. Timeframe concerns will be alleviated by closely monitoring progress with the project supervisor to ensure continuous progress. Remaining ahead of the timeline where possible will provide a buffer, negating many effects of time loss due to illness. Legal/reputational risks to the university and researcher are possible, though unlikely, and will be managed through continual monitoring.

3.7. Section Conclusion

This section has discussed research and development methods, including associated factors such as ethical concerns, risks, and the timeline. Methods consist primarily of software development and UX testing, supported by a literature review and unstructured interviews. The next section evaluates and concludes this proposal.

4. Evaluation and Conclusion

This research aims to evaluate whether web applications can increase patient agency and increase clinician productivity and involvement. This is applied within the scope of Urological patients in Swansea who are searching for clinical trials. This work will develop a centralised trial searching application tailored for patients, facilitating data gathering. Data will be gathered from clinicians, while patients will be represented by non-patients due to access and ethical limitations, as a result of time limitations.

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Appendix – Draft Usability Testing Document

Patient Portal Usability Evaluation

This is a usability test of a web application which was developed to help patients find medical trials for their condition. For this evaluation, you will take on the role of the patient who is searching for trials and use a web application. You will be provided with medical and other contextual details for the patient you are portraying. Your participation is anonymous, and you may withdraw from this research at any point.

Please note: You are not being tested; rather, you are testing the application

Consent

This usability testing includes some medical topics which some participants may find upsetting.

Please indicate that you consent to participating in this research and your anonymised responses being used.

☐ I consent

Please provide some basic information about yourself before starting:

These questions are anonymous and will be used to determine patterns in data.

1. What is your gender?

☐ Male ☐ Female ☐ Other ☐ Prefer not to say

2. Which age range do you fall within?

☐ 18-24 ☐ 25-34 ☐ 35-44 ☐ 45-54 ☐ 45-54 ☐ 55-64 ☐ Above 64

☐ Prefer not to say

3. Do you consider yourself to have any disability, particularly vision impairments, for example colour blindness? If so, please list, otherwise, please say no:

☐ Prefer not to say

Evaluation Instructions:

Go to the below address in your preferred browser:

<https://www.placeholder.com>

Index of /clinical-trials

If you see a page like the following screenshot, click **patient-portal/**, as is highlighted.

Name	Last modified	Size	Description
 Parent Directory		-	
 DataHandling/	2022-01-30 22:49	-	
 database.sql	2022-01-30 19:12	61K	
 get-survey-responses.>	2022-03-06 15:56	475	
 js/	2022-01-26 19:08	-	
 mail/	2022-01-17 16:16	-	
 noscript-header-styl.>	2022-01-27 18:53	151	
 noscript-message.html	2021-12-20 16:06	622	
 patient-portal/	2022-02-23 10:51	-	
 privacy-policy-popup.>	2022-01-30 22:49	9.5K	
 privacy-policy-texts.>	2022-01-29 16:30	1.7K	
 staff-portal/	2022-03-15 19:39	-	
 styles/	2021-12-17 18:10	-	
 survey-response-gene.>	2022-03-06 16:02	-	
 trial-files/	2022-02-15 21:21	-	

What you see next will be the patient home page. This is what you would see as a patient, having been referred to this website by your clinician. Your steps to test the website are detailed on the next page.

Your patient details:

These are the details you should use when navigating the web application. Put yourself in the shoes of someone with these details. **Note that as well as your below patient details, your consultant has advised you that there are some trials using Aspirin which may be suitable for you.**

Basic details

Condition specialty:	Urology
Affected organ:	Prostate
Condition name:	Localised prostate cancer
Age:	43
Gender:	Male
City of residence:	Swansea

Additional information

Have any other conditions?	No
Had any treatment?	Radiotherapy
Any medicine allergies?	No

Now follow these steps on the website:

1. From the home page, navigate to the trial search page.
2. Work through the trial search form using your allocated clinical details.
3. You will then be presented with a list of trials matching your eligibility criteria. View the first trial in the list.
4. Check if this trial is suitable for you.
 - a. Firstly, check the location of the trial is the same as your allocated town/city. If not, go back a page and view the next trial.
 - b. Once you have found a trial in your location, use the page's step-by-step form to check you are eligible for the trial **based on your allocated clinical details**. If the form tells you that you are eligible, move on to the next step. If you are not eligible, go back a page and choose the next trial, repeating this step.
5. Now that you have found a trial you are eligible for, please contact the trial's contact point using the website. Provide the below details:

Title: Mr
First name: User
Last name: Experience
Phone: 01234567890 (*No spaces*)
Email: *Leave blank*

6. Finally, in addition to having sent your contact details to the trial contact point, find the contact point's phone number from the page, and list it below:

Contact point phone number:

Now you have used the web application, please complete the questions on the following pages to evaluate it.

Based on your experience of using the website, please fill in the below System Usability Scale check boxes to reflect your honest opinion – this system will eventually be used by real patients, so evaluation and feedback is important.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I think that I would like to use this system frequently.	☐	☐	☐	☐	☐
I found the system unnecessarily complex.	☐	☐	☐	☐	☐
I thought the system was easy to use.	☐	☐	☐	☐	☐
I think that I would need the support of a technical person to be able to use this system.	☐	☐	☐	☐	☐
I found the various functions in this system were well integrated.	☐	☐	☐	☐	☐
I thought there was too much inconsistency in this system.	☐	☐	☐	☐	☐
I would imagine that most people would learn to use this system very quickly.	☐	☐	☐	☐	☐
I found the system very cumbersome to use.	☐	☐	☐	☐	☐
I felt very confident using the system.	☐	☐	☐	☐	☐
I needed to learn a lot of things before I could get going with this system.	☐	☐	☐	☐	☐

Final questions on the next page.

Putting yourself in the position of the patient, what did you like the most about the website?

Similarly, what gave you difficulty if anything, and what did you like the least about the website?

Finally, do you have any other feedback about the site, potentially future improvements?

THANK YOU FOR YOUR TIME.
YOUR FEEDBACK WILL POWER RESEARCH AND HELP FUTURE PATIENTS.