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Hub: North West	University: University of Liverpool
Supervisor Susanna Dodd s.r.dodd@liverpool.ac.uk	Duncan Appelbe Paula Williamson
Is the project clinical or non clinical? Non-Clinical	
Title of PhD project: Web usage data in clinical trials – how can we determine dose?	

Background: The use of web based interventions in clinical trials is on the increase (with a recent literature identifying in excess of 2800 journal articles relating to online intervention trials), as the internet provides an accessible mechanism for delivering intervention without the need for participants to travel to a clinic. However, it does not appear that the effectiveness of web interventions is being linked back to the actual usage of the intervention.

Collection of intervention use, or "dose", data is becoming increasingly important, in order to inform "causal" analysis methods accounting for actual intervention use (rather than simply analysing according to randomisation, using "intention to treat"). In the context of an online intervention, however, it is not immediately obvious how best to define and measure "dose".

Participants' use of an online intervention can be recorded and monitored using various techniques, including Google Analytics (GA), server log data and customisable call backs to the projects servers; however, the reliability of these approaches is not guaranteed. In particular, it is likely that many users are unaware of the inaccuracies associated with GA data.

This project seeks to guide trialists on best practice of collection and use of online intervention usage data, to ensure consistent and reliable comparisons of web intervention "dose" to be evaluated across studies. This guidance material would ultimately be offered as an extension to CONSORT guidelines, relating specifically to the design, conduct and analysis of online intervention trials.

Project Objectives The aim of this project would be to:
1) undertake a literature review to ascertain current practice among online intervention trials in terms of collecting, reporting and analysing web usage data
2) use in-house generated web usage data and data collected for the REACT trial (an online trial evaluating the effectiveness of a peer supported self-management intervention (Relatives Education And Coping Toolkit) for relatives of people with psychosis or bipolar disorder) to compare GA data with in-house server log and video data, in order to demonstrate the extent of GA inaccuracies and determine best practice for capturing accurate representation of web usage (on features such as video and page downloads, module use and navigational patterns, allowing for time away from screen, multiple browsers, mouse hovering etc.)
3) demonstrate how to use web usage data (from REACT trial) to inform causal analyses (adjusting for patterns of navigational sequencing and module use in order to ascertain whether certain patterns of web use correspond to improved outcome) as an example of how to apply causal analysis in this field
4) develop guidelines and toolkit for trialists on how best to collect, report and analyse web usage data as part of online intervention trials.

Supervision: The primary supervisor will be Dr Susanna Dodd, who has recently completed an NIHR doctoral research fellowship investigating the application of causal analysis methods in randomised trials with survival outcomes. Co-supervision will be provided by Dr Duncan Appelbe (Information Systems Manager, CTRC and co-chair HTMR Health Informatics group), and Prof Paula Williamson (Director NWHTMR Hub). DA will provide advice and direction in any technical aspects of this PhD. Prof Williamson will contribute trials methodological expertise.

Collaboration: This project will develop collaboration with Ian White (UCL, CTU hub), who will provide statistical expertise on the application of causal methodology. An existing collaboration with the Spectrum Centre for Mental Health Research at Lancaster University (REACT trial) will be strengthened and links with research on User Interface design and usage analysis (Jason Alexander and Borja De Balle Pigem, Data Science Institute) undertaken at Lancaster will be utilised. Professor Chris Hollis (Director, NIHR MindTech HTC, University of Nottingham) will provide expertise on development and implementation of digital technologies to assess, treat and monitor mental health disorders.

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Supplementary information

1. Describe the alignment of the project with the HTMR Network strategy

This project will promote high quality collaborative research between groups based at Liverpool and Lancaster to develop an understanding of how web analytics data can be used to quantify "dose" in a trial, culminating in a guidance document to promote best working practice in trials of online interventions. A longer term objective for this project is the development and publication of a CONSORT extension relating specifically to online intervention trials.

The project will also support cross-hub collaboration between Liverpool (NWHTMR hub) and UCL (CTU hub), with guidance provided from Ian White based on his experience with online intervention trials and statistical expertise on the application of causal methodology in clinical trials.

The project links specifically to the MRC's strategy relating to Health informatics, namely to "harness information contained within clinical, population, cellular and molecular datasets to gain new scientific insights into health and wellbeing". One of the key strategic elements underpinning this aim is the development of "infrastructure, tools and technologies to enable data collection, management, storage, analysis and linkage". This proposal also links with the rational for the development of the MRC Health Informatics collaborative (HIC), the aims of which include creating models "to check that data can be sensibly compared and what transformations, if any, are needed".

In addition to the overarching MRC strategy and reasoning behind the HIC, this proposal is aligned with the "analysis", "interpretation" and "reporting" aims of the HTMR network as it seeks to develop methodology in the area of web based interventions.

2. Does this project align with the work of a HTMR Working Group; if so, which?

This project links to the work of the Health Informatics Working Group and the student would be included within this Working Group.

3. Describe how this project aligns with the host Hub strategy

This project links to Theme 2 (Later phase trial design and analysis) of the NWHTMR, in particular by seeking to provide guidance on data collection, reporting and analysis of later phase trials involving online interventions.

4. Detail of any Project specific training offered in the studentship

The student would be provided with all relevant IT and statistical training by the primary supervisor, CTRC IS team and colleagues at the Lancaster Data Science Institute, Nottingham and UCL. A PhD advisory committee will be convened, consisting of Ian White (UCL, CTU hub), Professor Fiona Lobban (CI of REACT trial), Professor Chris Hollis (Director of NIHR MindTech HTC), Dr Borja De Balle Pigem (Lecturer in Data Science at the University of Lancaster specialising in statistical inference from web navigation data) and Dr Jason Alexander (Lecturer in the School of Computing and Communications at Lancaster University specialising in streamlined multimodular web design).

5. Are there any prerequisite qualifications or experience for this studentship?

Candidates for an MRC-funded studentship must meet residence eligibility and hold qualifications in a relevant subject at the level of, or equivalent to, a good honours degree from a UK academic institution (see methodology website for more details- www.methodologyhubs.mrc.ac.uk).

For this project: This studentship requires a degree/Masters in a relevant discipline demonstrating statistical/numerical skill, as well as the standard residence eligibility criteria applicable to all MRC-funded studentships.