# Usage metrics of web-based interventions: a systematic review of randomised controlled trials

Koneska E, Appelbe D, Williamson P, Dodd S\*

**\*Corresponding author**

Dr Susanna Dodd

Department of Biostatistics

Institute of Translational Medicine

University of Liverpool

Liverpool L69 3GS

UK

Phone: 0151 794 9752

Fax: none available

Email: s.r.dodd@liverpool.ac.uk

## Abstract

### Background

The evaluation of web-based interventions (defined as an intervention that can be downloaded or accessed via the Internet through a web browser) in randomised controlled trials has increased over the past two decades. Little is known about how participants’ intervention use is measured, reported and analysed in these studies.

### Objective

To review the evaluation of web-based interventions in randomised controlled trials, assessing study characteristics and the methods used to record, and adjust for, intervention usage.

### Methods

A systematic review of the literature was undertaken to identify all published reports of randomised controlled trials that involved a web-based intervention. A random sample of 100 published trials were selected for detailed data extraction. Information on trial characteristics were extracted, including whether web usage data were recorded, and if so, the methods used to gather these data and whether these data were used to inform efficacy analyses.

### Results

A PubMed search identified 812 trials of web-based interventions published up to the end of 2017 and demonstrated a growing trend over time. Ninety of the 100 studies reviewed collected web usage data, but more than half (49, 54%) of these studies did not state the method used for recording web usage. Only four studies attempted to check on the reliability of their web usage data collection methods. Thirty-five (39%) studies reported patterns or levels of web intervention use, of which 19 (21%) adjusted for intervention use in their outcome analysis, but only two of these used appropriate statistical methods.

### Conclusions

Trialists frequently report a measure of online intervention usage, but do not always report the collection method or provide enough detail on their analysis of web usage. Appropriate statistical methods to account for intervention use are rarely used and are not well reported even in the very few trials which use them. The number of trialists who attempt to check on the reliability of their web usage collection methods is extremely low.

## Keywords

Internet; web-based interventions; randomised controlled trials; web usage data; systematic review

# Introduction

## Randomised controlled trials

A randomised controlled trial (RCT) is used to assess the efficacy or effectiveness of an intervention by randomly dividing trial participants into experimental or control treatment arms, thereby providing a fair comparison for the unbiased assessment of treatment effects [1-4]. Traditionally trials have predominantly been conducted in a clinic setting; however, with the increase of the Internet as a mainstream communication channel, there has been an increase in the use of E-Mail, SMS and social media for communication and the delivery of interventions [5, 6].

## Web-based interventions

We define a web-based or online intervention as “downloadable or accessible via the Internet through a web browser”, which can take the form of (but not limited to) a website, E-mail or a web message board. There are various definitions of web-based interventions, some of which include social media and mobile phone applications; however, for the purposes of our review (in particular our interest in assessing web usage data), we were interested in confining our search to studies that would have been able to assess usage, which until relatively recently was not easy with social media or phone apps. As such, we restricted our definition of web-based interventions accordingly; however, our chosen definition is very similar to that provided by Barak [7].

With an estimated 4.4 billion people being active Internet users as of April 2019 [8], an increasing proportion of the global population are potential users of web-based interventions, particularly given the convenience and flexibility of such interventions. As such, these interventions have enormous potential to improve health and healthcare delivery and can be very accessible to patients [1, 9-11].

## Monitoring web usage

In the same way that drug treatments may be prescribed at a certain dose, trial participants receiving a web-based intervention may be advised to use the intervention to a specified degree (for example, in terms of duration or frequency of intervention use). If it is of interest to determine whether trial participants adhered to the recommended intervention “dose”, it is important to be able to track participants’ intervention use. There are multiple published reviews relating to online intervention usage. For example, Kelders et al [12] reviewed the literature to investigate whether study design predicts adherence to a web-based intervention, while Perski et al [13] reviewed the literature on digital behaviour change interventions in order to identify develop a framework linking direct and indirect influences on engagement and the relationship between engagement and intervention effectiveness.

There are numerous automated tools that can be used to track and record a participant’s web intervention use [14]. These tools can be split into two categories, either client (browser) based or server based. Client based tools, such as Google Analytics (GA) [15], rely on the web browser supporting them (e.g. JavaScript being enabled) [16] whilst server based tools such as web-server log data [17] will always be populated, as they record what data are sent to the client. These tools provide information about participants’ web intervention use, such as which web pages a participant has visited and when a web page has been accessed. The reliability of these tools is not guaranteed, however. Some tools which have been adopted by researchers to measure web usage, such as GA, were not originally designed for accurate reporting of web usage but were instead developed as a marketing aid. As such, whilst being easily accessible and commonly used, GA may not be the most appropriate tool to use in scientific research [18]. For example, prior research by OBrien et al [19] has demonstrated that 58% of activity on a website is unreported by GA.

In order to link intervention usage to a particular participant, rather than just obtaining general information about overall intervention use by all participants, each participant requires a unique identifier (UID), such as the study randomisation number or a username [20]. The use of a UID facilitates statistical analyses by linking intervention use with outcome data on an individual participant basis. Such data can then be used to inform statistical analysis in order to estimate the efficacy of the intervention received, rather than simply the effectiveness of intervention as randomised (as estimated by intention to treat, ITT, analysis). Commonly used methods to estimate efficacy, utilising participants’ usage of assigned intervention, include as-treated, per protocol analysis and completer analyses [21]. However, the use of these methods when a trial is subject to deviations from randomised treatment may introduce bias, and more appropriate causal methods should be used, such as complier average causal effect (CACE) analysis [22, 23].

## CONSORT and CONSORT-EHEALTH guidelines

The Consolidated Standards of Reporting Trials (CONSORT) [24] guidelines were introduced in 1996 to improve consistency and quality of reporting in RCTs. To address the specific challenges of web and mobile-app based intervention studies, the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth (CONSORT-EHEALTH) extension was published in 2011 [25]. This extension encourages trialists to report on participants’ intervention use; subitem 6a-ii of the CONSORT-EHEALTH extension states that researchers should “explain how use and engagement was measured and defined” and subitem 17-I states that “use and usage outcomes should be reported”. The intended benefit of these guidelines will, however, only be realised if they are adhered to; as such, it is important to assess their uptake in trials which have been published since their release.

## Aims and objectives

This systematic review was conducted to ascertain the extent and nature of web-based intervention use in trials and the current practice among trialists in terms of collecting, reporting and analysis of web usage data. We were also interested in determining the characteristics of such trials, including the types of design, intervention format and clinical areas.

# Methods

## Literature search

An initial systematic search of PubMed was conducted to ascertain whether there had already been any comprehensive systematic reviews of web-based intervention trials published to date (see Appendix Table 1 for search terms). [12, 13] [12, 25] The electronic database PubMed [26] was then searched to identify all web-based intervention trials published by the end of 2017 (see Table 1 for search terms). The protocol for this review has been published in the International Prospective Register of Systematic Reviews (PROSPERO) [27].

## Eligibility screening

Following removal of duplicate records, all remaining abstracts identified through the PubMed search were screened by author E.K to assess eligibility. Only RCTs involving a web-based intervention and published by the end of 2017 were eligible. Studies were excluded if they did not involve a web-based health intervention (e.g. educational studies) or were non-randomised (e.g. feasibility studies that did not involve randomisation, observational studies, quasi-randomised studies, surveys), secondary analyses, trial protocols or systematic reviews. Where there was any uncertainty regarding eligibility, authors D.A and S.D were consulted, and any disagreements were resolved by consensus. The eligibility of 5% (77) of the abstracts were randomly selected and reviewed by authors D.A and S.D to validate this process, on which there was 100% agreement.

## Data Extraction

One hundred studies were randomly selected from the cohort of eligible trials identified in this search, with sampling proportional to the annual distribution of publication years across the entire set of eligible studies. The initial data extraction form was piloted on five studies and refined accordingly. The final dataset included the study characteristics; whether a CONSORT flow diagram and a CONSORT-EHEALTH checklist were reported; whether treatment protocol deviations (i.e. changes to randomised online intervention) were reported; the methods used to collect web usage data; and which statistical analysis methods were used to adjust for intervention use.

Table Search terms for published web-based intervention trials

|  |
| --- |
| (online[tiab] OR digital[tiab] OR web-based OR web) AND internet[majr] AND (“Randomized Controlled Trial” [Publication Type] OR randomized control trial OR randomised control trial OR controlled trial OR controlled clinical trial OR RCT) (PLUS manual entry of upper limit of 31/12/2017 for date published) |

# Results

## Review of systematic reviews of web-based intervention trials

The PubMed search for systematic reviews of web-based intervention trials identified 271 citations, 123 of which were found to be eligible following review of titles and abstracts. These SRs covered a wide range of clinical or methodological areas, most commonly health promotion (47, 38%) and mental health (40, 33%) (see Appendix Table 2). None of these systematic reviews included a comprehensive search of all published online health intervention trials.

## Review of web-based intervention trials

The electronic database search for trials of web-based interventions yielded 1726 publications (see Figure 1). After removing nine duplicates, there were 812 eligible and 906 ineligible studies based on the review of abstracts, including one publication identified manually as the original trial report relating to another publication identified in the search. Of the 100 eligible studies selected for data extraction, six were subsequently excluded after reading the full publication. These ineligible studies were replaced with an additional six eligible studies for data extraction.



Figure 1 Search and screening process

## Published web-based intervention trials

The number of published trials involving web-based interventions is displayed in Figure 2, demonstrating an increasing trend over time. However, despite this increase, the number of trials utilising web-based interventions remains proportionally low when compared to the total number of trials during this period (estimated as 496,238 from a PubMed search filtered to only include trials published up to the end of 2017). The reduction seen after 2015 is likely to be due to publications not being fully indexed or registered within the PubMed database when the search was run (12/02/2018). A PubMed librarian confirmed that new publications may be posted on PubMed significantly later than their publication date [28].



Figure 2 Number of published and sampled trials of online intervention trials each year

## Description of studies and study characteristics

The characteristics of the 100 publications randomly selected for data extraction are given in Table 2. Most of these studies covered health promotion (42%, most commonly smoking cessation, physical activity and weight) and mental health (32%).

The vast majority of trials had a superiority design and did not use blinding or did not state whether there was any blinding. Thirteen studies reported being single-blind (six reported blinding of the assessors, six of the patients and one of the clinician) and only one study reported being double-blind (patients and assessors). In the 86 trials which stated that there was no blinding or did not mention blinding, the web-based and control interventions took different formats (most commonly a website intervention versus a wait list (25) or non-Internet (18) intervention), which would have made it difficult to blind participants.

Table 2 Characteristics of 100 sampled trials

|  |  |  |
| --- | --- | --- |
| **Clinical area**  |  | **Number (=% out of 100 trials)** |
| Health Promotion  |  |  | 42 |
|  | Smoking cessation  | 11 |  |
|  | Physical activity  | 8 |  |
|   | Weight | 7 |  |
|  | Alcohol | 3 |  |
|  | Eating disorder  | 3 |  |
|  | Lifestyle behaviours  | 2 |  |
|  | Physical activity and diet  | 2 |  |
|   | Diet | 2 |  |
|  | Sexual Health  | 1 |  |
|  | Tanning | 1 |  |
|  | Adolescent health  | 1 |  |
|  | General health management  | 1 |  |
| Mental Health |  |  | 32 |
| Cancer |  |  | 4 |
| Respiratory Illnesses |  |  | 3 |
| Neurology |  |  | 3 |
| Diabetes |  |  | 3 |
| Dentistry  |  |  | 2 |
| Otolaryngology  |  |  | 2 |
| Cardiovascular  |  |  | 2 |
| Pain  |  |  | 1 |
| Autonomic Arousal  |  |  | 1 |
| Discharge from Emergency Dept  |  |  | 1 |
| Parathyroid disorder  |  |  | 1 |
| HIV  |  |  | 1 |
| Cancer screening  |  |  | 1 |
| Women's Health  |  |  | 1 |
| **Design** |  |  |  |
|  | Superiority |  | 94 |
|  | Equivalence |  | 4 |
|  | Non-inferiority |  | 2 |
| **Blinding** |  |  |  |
|  | Double |  | 1 |
|  | Single |  | 13 |
|  | None |  | 46 |
|  | Not stated |  | 40 |
| **Web-based intervention** |  |  |  |
|  | Website |  | 77 |
|  | Website plus additional element |  | 10 |
|  | Internet (Other)  |  | 13 |
| **Control arm** |  |  |  |
|  | Website |  | 14 |
|  | Internet (other) |  | 14 |
|  | Waiting list group |  | 32 |
|  | Non Internet intervention  |  | 28 |
|  | No intervention |  | 9 |
|  | Not stated |  | 3 |
| **CONSORT flow diagram presented**a |  | 79 |
| **CONSORT-EHEALTH checklist presented**b |  | 26 (38.2) |

a Denominator for % is equal to 100, as all trials were published after the original CONSORT flow diagram (1996).

b Denominator for % is equal to the number of trials published since CONSORT-EHEALTH (2011) (n=68).

The majority of studies involved a website as the intervention; other interventions included a podcast, E-mails, web applications, web video camera, computer simulation, computer generated photo aging intervention, web-message boards, Internet partner, YouTube video, online video and Internet video conference. Ten studies reported a website plus an additional element, which took the form of a mobile app, online video, social media, interactive voice response, personal activity monitor, personal digital assistant or an online forum. The most common type of control arm intervention was waiting list (delayed treatment) followed by non-Internet interventions (face-to-face intervention, written materials and treatment as usual). Table 3 displays the crosstabulation of web-based and control interventions in the 100 sampled trials.

Table 3 Web-based and control interventions

|  |  |  |
| --- | --- | --- |
| **Control intervention**  | **Web-based intervention** |  |
| Website | Website plus additional element | Internet (other)  | **Total** |
| Website | 12 | 2 | 0 | 14 |
| Internet (other) | 10 | 0 | 4 | 14 |
| Waiting list group | 26 | 2 | 4 | 32 |
| Non-Internet intervention  | 20 | 4 | 4 | 28 |
| No intervention | 6 | 2 | 1 | 9 |
| Not stated | 3 | 0 | 0 | 3 |
| **Total** | 77 | 10 | 13 | 100 |

Seventy-nine of the 100 studies included a CONSORT flow diagram, whilst 26 (38% of the 68 studies published after the CONSORT-EHEALTH guideline, 2011) included a CONSORT-EHEALTH checklist (Table 2).

The publication of CONSORT-EHEALTH does not appear to have positively influenced the rate of reporting web usage (Table 4).

Table 4 Rates of reporting web usage data according to publication year and CONSORT-EHEALTH checklist reporting

|  |  |  |
| --- | --- | --- |
| **Publication year** | **Reported web usage data** | **Total** |
| Yes | No |
|  |  |  |  |
| $\leq $2011 | 30 (93.8%) | 2 (6.2%) | 32 |
|  |  |  |  |
| $>$2011 | Included CONSORT-EHEALTH checklist | Yes | 22 (84.6%) | 4 (15.4%) | 26 |
| No | 38 (90.5%) | 4 (9.5%) | 42 |
| **Total** | 90 | 10 | 100 |

Out of 26 trial publications that included a CONSORT-EHEALTH checklist, four did not report whether web usage data were collected. There were different reasons for not reporting usage in these four publications: one trial acknowledged collecting usage data with the intention to publish usage in a separate publication; one trial did not collect usage due to privacy protection (with no further explanation); one trial gave no explanation on why usage was not collected and it was not possible to access the CONSORT-EHEALTH checklist in the fourth trial (due to an expired or invalid checklist hyperlink).

## Collection and reporting of web usage data

Commonly used formats for the online intervention included sessions (17 trials), modules (13), content (13) and assignments (5). Other formats included cartoons, messages, videos, photographs and various tasks or exercises. Examples of these interventions included a brief personalised normative feedback system provided by various modes of delivery [29], identical content delivered as a podcast or via a website [30] and website information to encourage and support a personalised physical activity plan [31]. One trial [32] used a computer-generated photo ageing intervention, with which participants were digitally photoaged and received a photograph of themselves as a lifelong smoker and as a non-smoker. Exercises took the form of mindfulness exercises as part of modules completion [33] and series of abdominal plank exercises whilst exercising with an Internet partner [34].

Web usage data were collected in 90 of the studies, but more than half (49, 54%) of these studies did not state the method used for recording the web usage. The most commonly reported tool used for tracking web usage was server or electronic log files (see Figure 3). Other methods included software tools, website tracking data, GA and self-reported data. Only four (4%) of 90 trial reports mentioned checking the reliability of their web usage measurement methods, two of which used more than two tools to capture and compare web usage data.

Figure 3 Web usage data collection methods among 90 trials which collected web usage data

Among the 87 trials involving a website, 78 (90%) recorded web usage data, most commonly in terms of number of logins (37, 43%), number of individual intervention components completed (21, 24%) (for example, assignments, exercises, lessons, modules), measures of activity on site (for example, answers entered, activated hyperlinks, blog or forum posts) (18, 21%) and time spent on site (18, 21%) (see Table 5). Thirty-one (36%) of these trials recorded a combination of two or more usage measures, most commonly number of logins and time spent on site (15 trials). Among the 23 trials involving an online intervention other than a website, 20 (87%) recorded web usage data, most commonly in terms of number of logins (6, 26%), video views (6, 26%) and measures of activity (5, 21%). Six (26%) of these trials recorded more than one usage measure (see Table 6).

Table 5 Features of web usage recorded among trials which involved a website

|  |  |
| --- | --- |
|  | **Number of trials** **(% out of 87 trials**a**)** |
| No web usage data collected | 9 (10.3) |
| Activity on site (e.g. answers, activated hyperlinks, blog/forum posts) | 18 (20.7) |
| Communication (e.g. emails, Skype calls, call logs, messages sent) | 3 (3.5) |
| Completed intervention (e.g. all assignments, exercises, lessons or modules) | 3 (3.5) |
| Number of individual intervention components (e.g. modules, sessions) started/accessed | 3 (3.5) |
| Number of individual intervention components (e.g. modules, sessions) completed | 21 (24.1) |
| Number of logins | 37 (42.5) |
| Number of page hits (individual actions, e.g. audio clips, scrolling, printing) | 1 (1.2) |
| Number of page views | 14 (16.1) |
| Time spent on site (including time spent listening to podcast) | 18 (20.7) |
| Video views (including YouTube views) | 1 (1.2) |

a Note that 24 trials included two measures of web usage, four trials included three measures of web usage and three trials included four measures of web usage.

Table 6 Features of web usage recorded among trials which involved a web-based intervention other than a website

|  |  |
| --- | --- |
|  | **Number of trials** **(% out of 23 trials**a**)** |
| No web usage data collected | 3 (13.0) |
| Activity on site (e.g. answers, activated hyperlinks, blog/forum posts) | 5 (21.7) |
| Communication (e.g. emails, Skype calls, call logs, messages sent) | 1 (4.4) |
| Number of individual intervention components (e.g. modules, sessions) completed | 3 (13.0) |
| Number of logins | 6 (26.1) |
| Number of page views | 3 (13.0) |
| Receipt of photographs | 1 (4.4) |
| Time spent on site (including time spent listening to podcast) | 2 (8.7) |
| Video views (including YouTube views) | 6 (26.1) |

a Note that five trials included two measures of web usage and one trial included three measures of web usage.

Forty (44%) of the 90 trials that collected web usage reported using UIDs, most commonly login credentials or IP addresses (see Table 7). An additional 11 (12%) publications reported the use of server or electronic logs to record web usage, both of which have the potential to include UIDs. Seven (8%) of the 90 trials implied having UIDs but did not state what type of UID was used.

Table 7 Unique identifiers

|  |  |  |
| --- | --- | --- |
|  |  | **Number (=% of 100 studies)** |
| **Web usage collected**  |  | 90 |
|  | Unique identifier  | 40 |  |
|  | Potential unique identifier (server/electronic logs) | 11 |  |
|  | Implied unique identifier but not specified  | 7 |  |
|  | No unique identifier | 3 |  |
|  | Not stated  | 29 |  |

Trialists reported changes to randomised online intervention (treatment protocol deviations) in 33 of the studies. Departures from randomised treatment included failing to initiate treatment (in 15 trials, for example when participants did not activate account, access site or log in), premature discontinuation of the intervention (in 18 trials, for example when participants withdrew from the trial or experienced difficulties using site); switching to an alternative arm, which was reported in two trials; and switching to non-online treatment, reported in two trials.

## Intervention dose

Sixty-nine trials from our sample specified a recommended dose of the online intervention, 62 (90%) of which measured web usage. Dose was specified in terms of sessions, modules, or assignments in 34 (49%) of these 69 studies (mean, SD = 2.8, 2.3; range = 1, 14). Of the 23 studies that reported a time frame for the use of the web-based intervention, the duration ranged from 1-12 weeks (mean, SD = 2.2, 1.3), with the exception of one study which reported a duration of 150 days (5 months). The average dose frequency was one task per week in 25 (36%) of the 69 studies that recommended a dose. Six studies (9%) reported that participants had more than one task to complete per week and seven studies (10%) reported that participants were due to complete tasks less frequently than one per week.

## Analyses involving web usage data

Only 35 (39%) of the 90 trials which collected web usage data investigated levels of intervention use (Table 8). Nineteen (21%) studies used statistical methods to adjust for intervention usage such as completer analysis (11 trials), regression analyses with intervention use as a covariate (six trials) and CACE analysis (two trials). One of the two trials that used CACE analysis did not present results or explain their method further, while the other trial presented CACE results and explained that this analysis estimates the potential efficacy among participants who would comply with their randomised intervention.

Table 8 Analyses involving web intervention use

|  |  |  |
| --- | --- | --- |
|  |  | **Number (=% of 100 studies)** |
| Any analysis involving web intervention use |  | 35 |
|  | Comparison of web intervention use between randomised arms  | 3 |  |
|  | Assessed patterns of web intervention use | 4 |  |
|  | Correlation between web intervention use and outcome  | 9 |  |
|  | Completer analysis  | 11 |  |
|  | Regression analyses with web intervention use as a covariate  | 6 |  |
|  | Causal analysis (CACE)  | 2 |  |

# Discussion

## Characteristics of web-based intervention trials and systematic reviews

Although the use of web-based interventions in RCTs has been on the increase over the last 15 years, unsurprisingly the number is still low in comparison to the overall number of published trials. A random sample of 100 trials suggests that online interventions are most commonly used for health promotion (42%) or mental health issues (32%), with the remaining 26% of trials covering 14 clinical areas, including cancer (4%), diabetes (3%) and neurology (3%). The review of systematic reviews of web-based intervention studies demonstrated a similar pattern, with 38% of reviews relating to health promotion interventions and 33% relating to mental health. All systematic reviews identified were restricted to trials within a certain clinical condition, other than the review by Mathieu et al [5], which only included trials that were fully or primarily conducted online (for example, involving online recruitment, consent, randomisation and follow up) while Lustria et al [35] reviewed trials which defined “ehealth”. As such, this review of systematic reviews demonstrated that there were no previously published reviews of all web-based intervention studies, providing evidence of the novelty and usefulness of the present study.

## Adherence to CONSORT and CONSORT-EHEALTH guidelines

Good quality reporting allows clinicians and researchers to replicate trial methods [36-38] and supports understanding of the trial methods, interventions and outcomes. This study suggests that there is a need for greater adherence to reporting guidelines in publications of web-based intervention trials. Less than 80% of the trials in our sample presented CONSORT flow diagrams, which is considerably less than the 96% reported to have presented CONSORT flow diagrams in a sample of 100 trials published in 2008 [21]. This may be due to the fact that CONSORT is less commonly endorsed by Health Informatics journals than clinical journals or is less familiar to trialists assessing web-based interventions than for clinical trialists generally.

Furthermore, although the CONSORT-EHEALTH guideline is listed on the EQUATOR website [39] and has been adopted by the Journal of Medical Internet Research, less than 40% of the studies published since CONSORT-EHEALTH included a CONSORT-EHEALTH checklist; the authors may therefore want to consider some of the strategies suggested by the EQUATOR network to increase use of guidelines [40], such as further dissemination via journal editorials or conference presentations, provision of online training or publicity via social media or blog posts. Improving awareness and uptake of the CONSORT-EHEALTH guidelines is important to ensure that the methodological quality of web-based intervention trials is clearly communicated, thereby allowing readers to make informed judgements on the validity of inferences and conclusions drawn in such trials.

## Reporting and analysis of web usage data

The CONSORT-EHEALTH guideline recommends reporting data collection methods and results relating to intervention use, but not all studies that included a CONSORT-EHEALTH checklist reported information on collection of web usage data. Indeed, the publication of CONSORT-EHEALTH does not seem to have influenced the quality of reporting regarding web usage, as the rate of reporting web usage data was higher before the publication of CONSORT-EHEALTH.

Unlike drug interventions, the adherence to which can be summarised using uncomplicated measures of treatment intake (for example, initiation, completion and persistence [21]), web-based interventions often involve multiple features [41, 42], engagement with which may be more complex to record. For example, it may be of interest to determine which precise areas of a webpage are read, whether videos are watched in their entirety or typical navigation patterns through a website, none of which would be trivial to capture. Our review demonstrated that trialists collect data on a wide variety of web usage features, most commonly number of logins, number of intervention components completed, activity and time spent on site. One third of the trials which recorded web usage information collected web usage data on more than one feature, the most common combination being number of logins and time spent on site. The likelihood of measuring web usage data did not vary according to whether or not participants were recommended to follow a specific dose (for example, when participants were asked to use the web-based intervention for a specific period of time or to complete a certain number of modules): the proportion of trials that measured web usage was equal to 90% in those trials which did, and in those which did not, specify a recommended dose. This suggests that the high rate of measuring web usage in web-based intervention trials is not necessarily due to trialists’ interest in assessing participants’ adherence to a recommended intervention dose; instead, web usage data are commonly recorded regardless of whether there is a recommended dose, demonstrating that such data appear to be of interest to trialists in their own right.

Trialists rarely provided a rationale for their choice of web usage metrics or analysis methods to adjust for web usage. Only two of the 15 trials which adjusted their outcomes for intervention use applied an appropriate method of causal analysis (CACE) to estimate efficacy, suggesting a lack of awareness regarding appropriate methods to account for the impact of participants’ intervention use on their outcomes.

## Assessing reliability of web usage data

Although automated capture of participants’ use of web-based interventions may be assumed to be more straightforward and reliable than the usual measures used to capture drug treatment intake (which typically involve participant self-report such as pill counts and treatment diaries, and therefore are potentially subject to recall bias or distortion), this is not necessarily the case. Assessing reliability of web usage data collection methods is therefore vital, but very few trialists in our sample mentioned checking the reliability of their web usage measurement methods. When trialists do not check the reliability of their web usage data collection methods, there is a potential for their web usage data (and any subsequent inferences based on these data) to be biased, particularly when inherent features of web usage differ between the randomised interventions. Van Rosmalen-Nooijens et al compared results from GA, content management system logs (CMS) and data files with self-reported data from participants and concluded that the usage information from the different sources corresponded well [43]. Nguyen et al [44] and Mermelstein et al [45] also aimed to assess the reliability of their methods but both studies reported a lack of reliability of their data due to technical or logistical issues. Similarly to drug trials, participants’ self-reported web usage may also misrepresent true use of the intervention [46]. For example, Fleisher et al found discrepancies between self-reported data and usage data obtained from the NetTracker software tool [47]. Fleisher reported that nearly 40% of the participants who reported using the website actually did not, while 20% of those who reported they did not use the website did in fact log in [47]. We are currently undertaking work to determine the reliability of different web usage collection methods, given the uncertainty regarding accuracy of certain methods.

## Strengths and limitations

This review was not designed to identify trials which utilised mobile phone applications or social media interventions. This was a conscious decision because our primary aim was to determine the frequency with which trialists monitored web usage.

The large number of eligible studies prohibited data extraction on all eligible trials; as such, it was decided that a random sample of these trials would be selected (using stratified sampling according to the year of publication in order to ensure that the publication year profile mirrored that of the complete cohort of eligible studies). Although only 100 of the eligible trial publications were therefore included in the data extraction exercise, we believe that this is a sufficient number to give reliable estimates (for example, ensuring estimation of proportions up to a maximum standard error of 0.05) and an accurate indication of trends in reporting and analysis.

The process of determining eligibility of web-based intervention trials was based on the review of abstracts only; as such some of the studies deemed as eligible may not have been, as evidenced by the exclusion of six of the studies from the sample of 100 studies. Also, only one reviewer carried out data extraction; however, this reviewer was able to consult the opinion of a second reviewer if in any doubt as to appropriate classifications.

This review is limited by the search of the online publications database of PubMed alone. The number of web-based interventions in 2016/7 will be underestimated from this search, due to delays in registration and indexing of studies within PubMed. PubMed indexes the majority of, but not all, Health Informatics journals; there are currently 286 Health Informatics type journals, of which 196 are indexed in PubMed. Therefore, our total of 806 trials cannot be taken as the absolute number of web-based intervention trials published up to the end of 2017.

## Conclusion

There is an increasing trend in the use of web-based interventions in RCTs. Tracking web usage data in such trials is necessary to establish the efficacy of web-based interventions. When an intervention is found to be less effective than desired, without usage data it is hard to determine if the problem is due to the intervention content or the lack of use of the intervention [47]. Information on participants’ intervention use should therefore be reported within trial publications, with particular focus on relevant features of participation which are likely to impact on outcomes. Although the majority of studies reviewed here reported a measure of online intervention usage, trialists often did not report sufficient detail about how the data were collected and rarely considered the accuracy of their web usage data collection methods. There was a modest degree of interest in investigating patterns of web usage, but very few trialists used an appropriate method of analysis to account for the impact of intervention use on participant health outcomes.

**Conflicts of Interests**

None declared

**Author contributions**

EK developed the protocol, carried out the search and data extraction, and drafted the manuscript. SD conceived the initial idea, helped to develop the protocol, acted as a second opinion on data extracted and commented on drafts of the manuscript. DA helped to develop the protocol, acted as a second opinion on data extracted and commented on drafts of the manuscript. PW helped to develop the protocol and commented on drafts of the manuscript. All authors read and approved the final manuscript.

**References**

1. Paul, J., R. Seib, and T. Prescott, *The Internet and Clinical Trials: Background, Online Resources, Examples and Issues.* J Med Internet Res, 2005. 7. PMID:15829477

2. Stanley, K., *Design of Randomized Controlled Trials.* Circulation, 2007. 115: p. 1164–1169. PMID:17339574

3. Kendall, J., *Designing a research project: randomised controlled trials and their principles.* Emergency Medicine Journal, 2003. 20(2): p. 164-168. PMID:12642531

4. Kabisch, M., et al., *Randomized controlled trials: part 17 of a series on evaluation of scientific publications.* Deutsches Arzteblatt international, 2011. 108(39): p. 663-668. PMID:22013494

5. Mathieu, E., et al., *Internet-based randomized controlled trials: a systematic review.* Journal of the American Medical Informatics Association : JAMIA 2012. 20,3. PMID:23065196

6. Pugatch, J., et al., *Information Architecture of Web-Based Interventions to Improve Health Outcomes: Systematic Review.* J Med Internet Res, 2018. 20(3): p. e97. PMID:29563076

7. Barak, A., B. Klein, and J. Proudfoot, *Defining internet-supported therapeutic interventions.* Ann Behav Med, 2009. 38(1): p. 4-17. PMID:19787305

8. *Statista*. [accessed 2019-27-12]. Available from:

 https://www.statista.com/statistics/617136/digital-population-worldwide/.

9. Wasilewski, M., J. Stinson, and J. Cameron, *Web-based health interventions for family caregivers of elderly individuals: A Scoping Review.* International Journal of Medical Informatics 2017. 103: p. 109-138 PMID:28550996

10. Andersson, G. and N. Titov, *Advantages and limitations of Internet-based interventions for common mental disorders.* World psychiatry : official journal of the World Psychiatric Association (WPA), 2014. 13(1): p. 4-11. PMID:24497236

11. Murray, E., *Web-based interventions for behavior change and self-management: potential, pitfalls, and progress.* Medicine 2.0, 2012. 1(2): e3. doi: [10.2196/med20.1741](https://dx.doi.org/10.2196/med20.1741) PMID:25075231

12. Kelders, S., et al., *Persuasive System Design Does Matter: A Systematic Review of Adherence to Web-Based Interventions.* J Med Internet Res 2012. 14(6). PMID:23151820

13. Perski, O., et al., *Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis.* Transl Behav Med, 2017. 7(2): p. 254-267. PMID:27966189

14. Payne, P., et al., *Improving Clinical Trial Participant Tracking Tools Using Knowledge-anchored Design Methodologies.* Applied clinical informatics, 2010. 1(2): p. 177-196. PMID:22132037

15. Google *Google Analytics*. [accessed 2019-27-12]. Available from:

 https://analytics.google.com/analytics/web/

16. Thushara, Y. and R. Vamanan, *A Study of Web Mining Application on E-Commerce using Google Analytics Tool.* International Journal of Computer Applications, 2016. 149: p. 975-8887.

17. Apache. *Log Files*. [accessed 2019-27-12]. Available from:

 https://httpd.apache.org/docs/1.3/logs.html.

18. Clark, D., D. Nicholas, and H. Jamali, *Evaluating information seeking and use in the changing virtual world: the emerging role of Google Analytics.* Learned Publishing, 2014. 27(3): p. 185–194.

19. OBrien, P., et al., *RAMP – the Repository Analytics and Metrics Portal: A prototype web service that accurately counts item downloads from institutional repositories.* Library Hi Tech, 2017. 35(1): p. 144-158.

20. Olden, M., et al., *IDGenerator: unique identifier generator for epidemiologic or clinical studies.* BMC Medical Research Methodology, 2016. 16(1): p. 120.

21. Dodd, S., I. White, and P. Williamson, *Nonadherence to treatment protocol in published randomised controlled trials: a review.* Trials, 2012, 13:84. doi: 10.1186/1745-6215-13-84 PMID:22709676

22. Dodd, S., I. White, and P. Williamson, *A framework for the design, conduct and interpretation of randomised controlled trials in the presence of treatment changes.* Trials 2017, 18(1):498. doi: 10.1186/s13063-017-2240-9. PMID:29070048

23. Bellamy, S., J. Lin, and T. Have, *An introduction to causal modeling in clinical trials.* Clinical Trials, 2007. 4(1): p. 58-73. PMID:17327246

24. Begg, C., et al., *Improving the quality of reporting of randomized controlled trials. The CONSORT statement.* Jama, 1996. 276(8): p. 637-9. PMID:8773637

25. Eysenbach, G., *CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions.* J Med Internet Res, 2011. 13(4): p. e126. PMID:22209829

26. PubMed [Internet]. [accessed 2019-27-12]. Available from:

 https://www.ncbi.nlm.nih.gov/pubmed.

27. Koneska, E., D. Appelbe, and S. Dodd, *Determining the extent of web-based intervention use in health research: a systematic review.* PROSPERO 2018. CRD42018095116.

28. Lead Customer Service Librarian, PubMed. Email correspondence on 12/2/2018.

29. Andersson, C., *Comparison of WEB and Interactive Voice Response (IVR) Methods for Delivering Brief Alcohol Interventions to Hazardous-Drinking University Students: A Randomized Controlled Trial.* Eur Addict Res, 2015. 21(5): p. 240-52.

30. Turner-McGrievy, G., S. Kalyanaraman, and M. Campbell, *Delivering health information via podcast or web: media effects on psychosocial and physiological responses.* Health communication, 2013. 28(2): p. 101-109. PMID:22420785

31. Irvine, A., et al., *Get moving: a web site that increases physical activity of sedentary employees.* Am J Health Promot, 2011. 25(3): p. 199-206. PMID:21192750

32. Burford, O., et al., *Internet-Based Photoaging Within Australian Pharmacies to Promote Smoking Cessation: Randomized Controlled Trial.* J Med Internet Res 2013. 15 (3). PMID:23531984

33. Boettcher, J., et al., *Internet-based mindfulness treatment for anxiety disorders: a randomized controlled trial.* Behav Ther, 2014. 45(2): p. 241-53. PMID:24491199

34. Irwin, B., D. Feltz, and N. Kerr, *Silence is golden: effect of encouragement in motivating the weak link in an online exercise video game.* Journal of medical Internet research, 2013. 15(6): p. e104-e104. PMID:23732514

35. Lustria, M., et al., *Computer-tailored health interventions delivered over the Web: review and analysis of key components.* Patient Educ Couns, 2009. 74(2): p. 156-73. PMID:18947966

36. Schroter, S., P. Glasziou, and C. Heneghan, *Quality of descriptions of treatments: a review of published randomised controlled trials* BMJ Open 2012, 2012. 2. PMID:23180392

37. Hoffmann, T., et al., *Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide.* BMJ : British Medical Journal, 2014. 348: p. g1687. PMID:24609605

38. Butcher, N., et al., *Improving outcome reporting in clinical trial reports and protocols: study protocol for the Instrument for reporting Planned Endpoints in Clinical Trials (InsPECT).* Trials, 2019. 20(1): p. 161. DOI: 10.1186/s13063-019-3248-0

39. Centre for Statistics in Medicine (CSM), University of Oxford. *Equator Network*. [accessed 2019-27-12]. Available from: <http://www.equator-network.org/>.

40. Centre for Statistics in Medicine (CSM), N., University of Oxford. *Equator Network Guideline*. [accessed 2019-27-12]. Available from:

 http://www.equator-network.org/toolkits/developing-a-reporting-guideline/disseminating-your-reporting-guideline/.

41. Kelders, S., et al., *Development of a web-based intervention for the indicated prevention of depression.* BMC Medical Informatics and Decision Making, 2013. 13(1): p. 26.

42. Ludden, G., et al., *How to Increase Reach and Adherence of Web-Based Interventions: A Design Research Viewpoint.* J Med Internet Res, 2015. 17(7): p. e172. PMID:26163456

43. van Rosmalen-Nooijens, K., et al., *Young People, Adult Worries: Randomized Controlled Trial and Feasibility Study of the Internet-Based Self-Support Method "Feel the ViBe" for Adolescents and Young Adults Exposed to Family Violence.* Journal of Medical Internet Research 2017. 19(6) e204. doi: 10.2196/jmir.6004. PMID:28606893

44. Nguyen, H., et al., *Randomized Controlled Trial of an Internet-Based Versus Face-to-Face Dyspnea Self-Management Program for Patients With Chronic Obstructive Pulmonary Disease: Pilot Study.* J Med Internet Res, 2008. 10(2)(9). doi: 10.2196/jmir.990. PMID:18417444

45. Mermelstein, R. and L. Turner, *Web-based support as an adjunct to group-based smoking cessation for adolescents.* Nicotine Tob Res, 2006. 1(Suppl 1) S69-76. PMID:17491173

46. Farvolden, P., et al., *Usage and longitudinal effectiveness of a Web-based self-help cognitive behavioral therapy program for panic disorder.* Journal of medical Internet research, 2005. 7(1): p. e7-e7. PMID:15829479

47. Fleisher, L., et al., *“ Build it, and will they come? Unexpected findings from a study on a Web-based intervention to improve colorectal cancer screening".* J Health Commun, 2012. 17 (1) 41-53. doi: 10.1080/10810730.2011.571338. PMID:22217118