Web usage data in clinical trials

Thesis submitted in accordance
with the requirements of the University of Liverpool for the
degree of Doctor in Philosophy
by

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April, 2022

Acknowledgements

I would like to thank my supervisors, Susanna, Duncan, Kerry and Paula for their devoted time, guidance and support. I am tremendously grateful to Susanna for being the most wonderful and supportive supervisor with a clear vision and detailed input on my work; Duncan for always being so responsive, dedicated, and an outstanding supervisor with clear thinking and new ideas; Kerry for wonderfully supporting me and guiding me through the qualitative research, and Paula for a clear and constructive feedback.

For financial support for the first three years of my PhD I would like to thank the University of Liverpool for the funding. I would also like to extend my gratitude to the Department of Health Data Science, particularly to Marta, Paula and Susanna for financially contributing towards some expenses after the end of my studentship. A big thanks to Nyree for being the best department administrator and going out of her way to always being a helping hand when needed.

I am thankful to all participants in the TRACK study and the focus group study for their time and effort, especially to those who participated in both studies.

Finally, I would like to thank my former employer and dear friend Toesef for his encouragement and motivation during those challenging days. He has been a bedrock of support and helped me to rise to every challenge during my PhD.

Abstract

The evaluation of web-based interventions in randomised controlled trials has increased over the past two decades. Little is known about how participants' usage of the intervention is measured, reported and analysed. When a trial participant visits and navigates a clinical trial website which involves a web-based intervention, they may perform different interactions that can be tracked with tracking methods. This thesis aimed to investigate usage data in clinical trials, providing a deeper insight into the tracking methods used and explore how to encourage usage and engagement with web-based interventions.

A systematic review was undertaken to ascertain current practice among web-based intervention trials in terms of collecting, reporting and analysing web usage data. A mixed methods (TRACK) study was then conducted, including qualitative semi-structured interviews and an online survey to investigate trial teams' experiences of using tracking methods for web-based interventions. A tracking web usage project then examined further tracking methods in the context of these interventions. A test website was developed to facilitate assessment of various tracking methods, which were implemented, configured and used to evaluate various usage metrics to allow for a summary of their use, advantages and disadvantages. Finally, a qualitative study involving focus groups of trialists was conducted to investigate how to encourage participants' usage and engagement with web-based interventions.

Of 1727 studies identified in the systematic review, 812 trials of web-based interventions published up to the end of 2017 were eligible and demonstrated a growing trend over time. Ninety of the 100 sampled studies collected web usage data, but more than half (49, 54%) 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.

In the TRACK study, 16 trialists participated in 14 interviews and 12 online surveys were completed. The most frequently chosen tracking method was Google Analytics followed by a website platform feature, server logs and bespoke software. Trialists' most common reason for choosing the method was previous experience.

The tracking web usage project evaluated five tracking methods: server logs, Google Analytics, Open Web Analytics, Matomo and Amplitude. The accuracy of the methods was checked by testing seven usage metrics: page views, timestamps, logins, IP address, clicks, document downloads and external links. The findings from this project suggest that tracking methods can provide reliable data to trialists but at least basic technical knowledge is required to implement and use the methods.

A total of four focus groups were conducted involving 15 trialists, and findings suggest that a combination of various usage, subjective and more general metrics can be used to determine engagement. The majority of trialists recommended features that they found useful to increase usage and engagement with user experience being the highest ranked feature, including the participants' perspectives and the role of technology in web-based interventions.

Usage data are important for trialists to demonstrate whether interventions are beneficial and to link usage with the effectiveness of the web-based intervention. These data are most objectively obtained by tracking methods rather than participant self-report, and their utilisation is important for trialists to obtain reliable data. Findings from the thesis suggest that these tracking methods can be successfully implemented, configured and used in the context of web-based interventions. Combining usage data with qualitative data and other metrics such as attrition, reminders, and typing into intervention website leads to more detailed insight and evaluation of web-based interventions and outcomes. To increase usage and engagement, trialists are recommended to focus on the needs, views and perspectives of the participants. Web-based interventions should be designed incorporating features and designs to enhance interaction, including interactive features, human involvement, reminders and tailoring. Emerging technology should also be considered, considering the target population, current regulations, and computer and technology literacy.

Publications

Chapter 2 is based on the publication from Koneska E, Appelbe D, Williamson P, Dodd S (2020) "Usage Metrics of Web-Based Interventions Evaluated in Randomized Controlled Trials: Systematic Review", Journal of Medical Internet Research (JMIR), 2020;22(4): e15474, DOI: 10.2196/15474. The author 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.

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List of abbreviations

API – Application Programming Interface

App – Application

CACE – Complier Average Causal Effect

CBT – Cognitive Behavioral Therapy

CI – Clinical Investigator

CONSORT – Consolidated Standards of Reporting Trials

CONSORT- EHEALTH – Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth

CSS - Cascading Style Sheets

DPA – Data Protection Act

GA – Google Analytics

GDPR - General Data Protection Regulation

GP – General Practitioner

GTM – Google Tag Manager

HTML – Hypertext Markup Language

IIS – Internet Information Services

IS – Information Systems

ITT – Intention to Treat

JS – JavaScript

NICE - National Institute for Health and Care Excellence

PIS – Participant Information Sheet

PP – Per Protocol

RCT – Randomised Controlled Trial

SR – Systematic Review

UA – Universal Analytics

UI – User Interface

UID – Unique Identifier

URL - Uniform Resource Locator

UX – User Experience

1.Introduction

The ever increasing availability of access to the world wide web has opened up the ability to utilise the Internet as a tool and online interventions to be used to solve clinical problems (1). An increase in online interventions and trials has led trialists to question how best to measure and improve usage and engagement of participants (2). Trial participants' use of a web-based intervention can be recorded and monitored, providing an immediate indication of the degree to which each participant used their assigned intervention. This information on usage is crucial to determine how web usage and engagement impacts on participant' outcomes. Modern day web analytics tracking methods can be used to gather usage data. Some methods initially intended for marketing purposes have been adopted by researchers in this field (3).

However, their implementation and use for web-based interventions has yet to be explored. The reliability of these methods is not guaranteed and inaccuracies can be associated with the data.

The focus of this thesis was to explore and investigate web usage data in clinical trials, to determine the extent of its use in web-based interventions and how to assess them. It also examines how to implement and use different tracking methods to ensure best practice of collection of usage data. The popular topic of how to increase usage and engagement was also investigated. In particular, the following research questions were explored:

- What is the current practice among web-based intervention trials in terms of collecting, reporting and analysing web usage data?
- What tracking methods trialists do use to collect usage data and what is their experience with these methods?
- How can tracking methods be implemented and used in the context of web-based interventions, which are easiest to implement and extract data from, and which provide the most accurate data?
- How can usage of and engagement with web-based interventions be measured and encouraged among trial participants?

*Chapter 2 p*rovides a background on the topic of web usage data in clinical trials. It starts with the concept of clinical trials, focusing on randomised controlled trials (RCTs) that involve web-based interventions. Web usage data, their importance and an overview of how they can be gathered, analysed and reported is presented, as well as the most common terms in this field associated with usage data. An introduction into the tracking methods used to record usage metrics is also given.

In *Chapter 3 a* published systematic review (SR) of web-based interventions in RCTs is presented, evaluating the extent and use of these interventions in RCTs, their characteristics and how their web usage data are collected, reported and analysed. Tracking methods for collecting usage data are explored and whether trialists check on their reliability. This SR investigates whether patterns and levels of usage are reported as well as whether specific adjustment was made for intervention usage for any outcomes in the analysis.

Chapter 4 presents the TRACK study. This study seeks to explore the tracking methods that trialists use to gather usage data and their experience with the methods. The study involves mixed methods, including interviews and a survey with international trialists.

Chapter 5 presents the results of a tracking web usage project, which investigates and evaluates different tracking methods for recording usage. Data are simulated manually and via software to check the accuracy of the methods by testing commonly used usage metrics. The aim of is to develop recommendations regarding reliable tracking methods for use with web-based interventions and to demonstrate how these can be setup and adapted to be used in the context of web-based interventions.

Chapter 6 is dedicated to the focus group study. This work explored the topic of participants' usage and engagement with web-based interventions. Insight is gathered from international trialists to develop guidance on determining engagement; encouraging participant engagement and usage; and suggestions for design features to enhance usage and engagement.

Chapter 7 concludes the thesis with a discussion on the main findings from all chapters and recommendations for assessing web usage data in RCTs of web-based interventions and ideas for further research.

2.Background

2.1 Introduction

This chapter begins by describing clinical trials, focusing on randomised controlled trials that involve web-based interventions. It introduces the web usage data and their importance proving an overview of how those can be gathered, analysed and reported. Most common terms in this field associated with the usage data are presented. The intervention usage can be measured by specific metrics and the collection of these data is recorded by the use of the tracking methods which are described at the end of the chapter.

2.2 Randomised controlled trials

Randomised controlled trials (RCTs) are research studies which aim to determine the safety and efficacy of different interventions (4, 5). Examples of such interventions include drugs, behavioural interventions (e.g. therapy for mental health conditions, dietary plan or weight reduction regime) (6). New treatments can be compared with existing treatments or, in the case of conditions for which there are no available treatments, to placebos or no treatment (3).

RCTs need a clearly defined clinical question, a predefined population and informed consent from all participants (2). Before a clinical trial is conducted, a protocol is developed including all details about the interventions, participant eligibility, what is to be investigated, how and why.

Participants in RCTs are randomly assigned to one of the treatment arms so that trialists can make an unbiased assessment of treatment effects (2-5). This randomisation process is considered to be the most efficacious and powerful design in clinical research (6, 7). It can be achieved through random number generation and gives each study participant equal chance of being allocated to either treatment arm (8). After randomisation, participants are followed up prospectively to assess their outcomes (5). The final results and analyses are then used to determine the effectiveness of the intervention by determining differences between treatment groups in terms of outcomes (5). These results and their interpretation need to be analysed in detail alongside a constructive discussion (3).

The process of blinding is used to further eliminate bias in RCTs. Trials can be single-blinded, double-blinded or non-blinded (3). Blinding in RCTs refers to the process of disguising the treatment the participants are randomised to (9). The purpose of blinding participants to their treatment is that participants' attitude may potentially influence their response to the treatment. In double-blinded studies both the participants and trialists are blinded to ensure that the knowledge of the treatment does not impact the care received by participants or their perception of the treatment they are receiving.

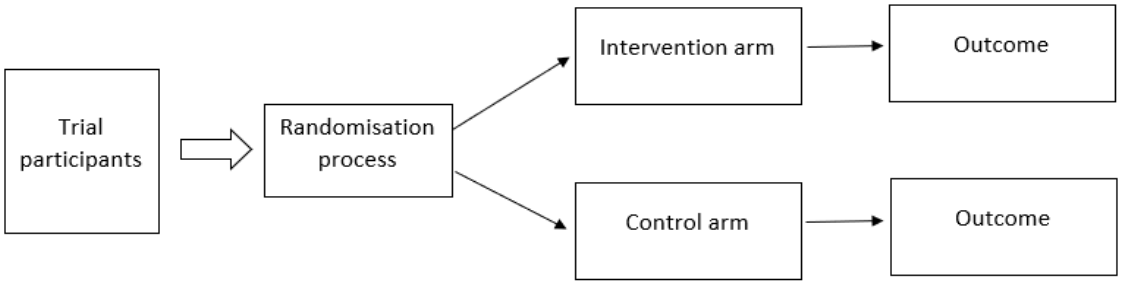


Figure 1. Pattern for a parallel group trial

Figure 1 shows the pattern for a parallel group trial, which is the most common and simple type of trial, but there are other types such as crossover or factorial (10). In a parallel group trial participants groups are randomised to one of the study interventions whereas in a crossover trial each participant is given series of all study interventions in a consecutive order (10, 11). A factorial design allows two or more interventions to be evaluated simultaneously, using four or more intervention groups (10, 12).

A cluster RCT involves randomisation of groups of participants to an intervention unlike individual level randomisation, where participants are allocated individually to an intervention (13, 14).

RCTs can be classified as “superiority”, “equivalence” or “non-inferiority” depending on their research hypothesis. Superiority trials are designed to prove that one treatment is superior to another (15) while equivalence trials aim to prove that the treatments are equivalent (with equivalence defined as “not too different” in a clinical manner) (2, 15). Non-inferiority trials are designed to establish that a new investigational treatment is not clinically inferior to an existing treatment (15).

Study participants need to fulfil the specified eligibility criteria so precisely defined inclusion and exclusion criteria are developed initially (3). In the past trial participants were recruited through contact with their physicians but since the emergence of the Internet and increased numbers of people with easy access to the Internet, participants can now be recruited online (2, 16). Online recruitment tools such as social media advertisements (for example, Facebook

or Google search engine advertisements) and other website campaigns can be used to recruit participants (16).

The flow of participants and their progress throughout the trial is often illustrated in publications via a flow diagram, which usually consists of the following sections: enrolment, intervention allocation, follow-up and data analysis. The Consolidated Standards of Reporting Trials (CONSORT) (17) flow diagram is the "gold" standard used by trialists (Figure 2). The CONSORT guidelines were introduced in 1996 to improve consistency and quality of reporting in RCTs (7).

The statistical methods used at the end to analyse data commonly include the ITT (intention-to-treat) or the PP (per-protocol) principle. In ITT analysis all study participants after randomisation are included regardless of withdrawal, discontinuation of randomised treatment, loss to follow-up or any other post-randomisation events (18). ITT analysis provides an estimate of the treatment effectiveness i.e., the effect of being randomised to the treatment, rather than the effect of necessarily receiving the randomised treatment. Variation of this method is the modified ITT (mITT) which excludes some study participants if this can be justified, for example excluding patients if they did not receive a minimum amount of study treatment (3, 18). PP analysis includes only those study participants who fully adhered to the study protocol (19). Completer analysis is another form of PP analysis which (depending on the specific definition stated) may relate to completion of the intervention or follow up (20).

Commonly used methods to estimate efficacy, allowing for participants' usage of assigned intervention, include PP (per protocol), as treated 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).

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

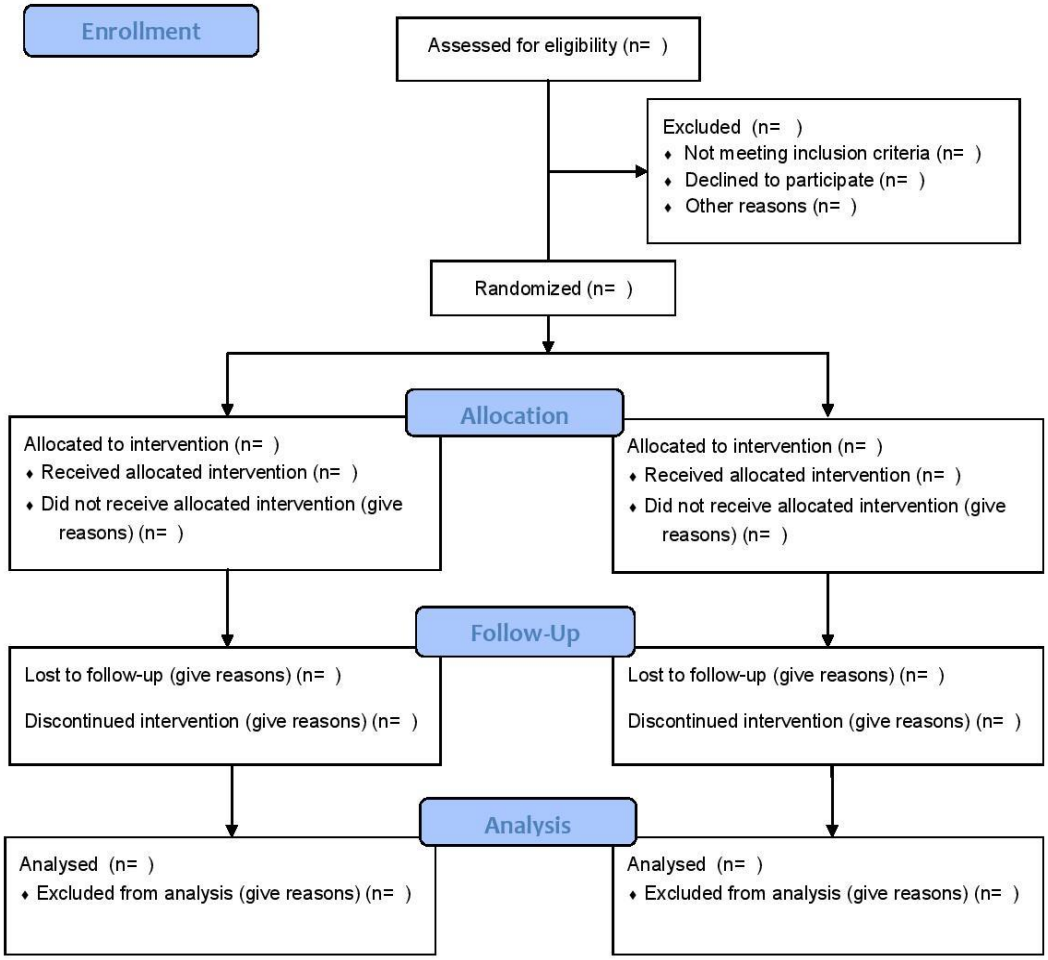


Figure 2. The CONSORT flow chart template (taken from the CONSORT website)

2.3 Clinical trials utilising web-based interventions

Traditionally trials have been conducted in a clinical setting; however, with the increase of the Internet as a mainstream communication channel, there has been an increase in the use of Internet, E-Mail, SMS and social media for communication between clinicians and study participants and the delivery of trial interventions (8, 9). In this thesis, a web-based or an online intervention is defined as one that is "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. Various definitions of web-based interventions are found in the literature, some of which also include social media and mobile phone applications.

Web-based interventions aim to increase knowledge and provide care or treatment to patients (10). They have been classified by Barak et al, (11) into three subtypes:

(1) web-based educational interventions;
(2) self-guided web-based interventions; and
(3) human supported web-based interventions.

Web-based educational interventions are used to provide educational information to participants (12). These interventions can help participants to acquire health information needed to assist them in the recovery process or educate them about their condition (12). An example of such an intervention is the web-based educational intervention for patients with uninvestigated dyspepsia referred for upper gastrointestinal tract endoscopy; this intervention aims to educate patients about dyspepsia and effectively decreases the need for upper gastrointestinal tract endoscopic procedures (13) .

Self-guided web-based interventions offer participants self-guided and structured program usually consisting of set of modules, lessons or interactive exercises to acquire self-help (14). These interventions usually consist of cognitive behavioural elements (14). An example of such an intervention is a self-guided intervention aimed at participants with gambling problems (15).

Human supported web-based interventions are web-based interventions that are supported by clinical personnel (11). An example of such an intervention is the therapist supported intervention for children and young people with tic disorders (16).

Web-based interventions may be suitable for a range of different health problems and are often used for health promotion and to support mental health. Examples include web-based interventions to promote physical activity; prevention and treating depression, anxiety, eating disorders; online mindfulness interventions; reducing or cession of drinking, gambling, smoking; web-based cognitive-behavioural therapy (CBT); self-management of long-term conditions such as diabetes and many others.

Due to the accessibility of the Internet and flexibility in modern browsers and mobile devices, clinical trials can now be conducted remotely i.e. where recruitment, consent, randomisation, intervention and follow up are all conducted online (4, 17). These are known as 'decentralised' trials; the REACT trial is an example of a fully online trial. REACT stands for The Relatives Education And Coping Toolkit, which is an online self-help toolkit for relatives of people with mental health problems like psychosis or bipolar disorders.

Advantages of these interventions are their convenience and flexibility as they can be accessed anywhere using the Internet. They can reach a diverse population including people living in rural and remote areas. As such, these interventions have enormous potential to improve health and healthcare delivery (4, 18-20) providing an accessible mechanism for delivering intervention without the need for participants to travel to a clinic or having to wait for a clinic appointment. However, issues can include inclusivity, the level of digital literacy and accessibility (21). Effective utilisation of these interventions can be limited if participants are lacking required technical knowledge, access to the Internet or suitable devices (21, 22). Concerns about this digital divide of people with and without full access to digital technologies have been recognised (22-24).

The National Institute for Health and Care Excellence (NICE) in the UK published their Evidence Standards Framework for digital health technologies (25) and Public Health England also published a guide on evaluating digital health products (26) which demonstrates increasing recognition that such interventions are important. The Covid-19 pandemic emphasised the usefulness of this way of delivering health care even further (27) as web-based interventions are all the more important in pandemic times. These interventions have the potential to protect patients and clinicians because they reduce the need for a face-to-face contact (27). Another advantage of these interventions is the low cost of access and use so they provide cost-effective solution health care (28, 29). They have the potential to reach patients at a low access cost (20) and to reduce the cost of travelling to a clinic for both

patients and medical personnel (30). The main cost associated with these interventions occurs at the development stage, so they are considered economical especially when used by higher number of people (20). These interventions can also be more discreet, and participants can feel more at ease than in face-to-face interventions (31) because they can preserve their privacy and anonymity. Participants can go through the intervention at their own pace without interference and this may encourage more participants to seek treatment and become involved (14).

In web-based interventions the treatment can be presented in specifically designed interactive components such as modules, assignments, lessons and exercises. These components can include text elements, videos, audio recordings, images, tests and interactive games. Use of interactive components allows simplification and visual presentation of complex information (20). These may all be available immediately, in which case participants can choose which component to access and complete. Alternatively, the components may only be accessible sequentially, such that subsequent components become available only on participant completion of previous components. The number of these interactive components varies per intervention. The length of web-based interventions also varies; some may be intended to last a short period of time (minutes or days) whereas others last much longer (weeks or months).

2.4 Usage, engagement, attrition and adherence as terms

Attrition or dropout refers to the loss of participants from study follow up (32, 33). Participants that drop out from a drug, surgery trials, physiotherapies or other treatments might have still had acquired positive clinical outcomes. Similar to this, in trials of web-based interventions if a participant drops out they may have interacted sufficiently with the intervention to obtain clinically significant benefits before dropping out of follow-up. A participant could, for example, complete all modules or assignments in a web-based intervention before dropping out. Conversely, a participant may complete all follow up but not use the web-based intervention at all. Trialists tend to report attrition but this is not sufficient to describe the level of interaction of the participants with a web-based intervention since the attrition rate does not indicate how much a participant has interacted with an intervention (34). Therefore, to show the amount of use of the intervention the term

"usage" is introduced. The term "usage" refers to the participants' degree of exposure to the intervention content (34-36). Usage can be measured by metrics such as time spent on using a program, the number of modules completed, how many logins to the intervention and various other activities that can be captured when a participant navigates a website intervention. In some trials, participants are sometimes required to "adhere" with the intervention to a certain level. Adherence in web-based interventions refers to the degree to which participants' interaction with the intervention content matches that intended usage pattern provided by trialists (34). For example, if the intended usage provided by trialists is that a participant should complete each of the five modules weekly and the participant completed only two on time that means that the participant was 40% adherent. When interventions are not prescribed with specific usage requirements, participants can choose the components that they want to complete in the order they want without needing to adhere to any specific guidelines i.e. the degree of use of the web-based intervention that they chose to engage with may well be optional. One possible advantage of this approach is when there is interest in obtaining insight into which modules engage participants the most (37). To encourage adherence trialists can use reminders, for example an automated reminder that a new module is available or a general reminder to use the intervention.

A particularly popular term relating to usage of web-based intervention is "engagement", which is used by trialists to explain the "real interaction" of participants with a web-based intervention (38). Engagement relates to the extent that the participant connects with the content of the intervention. It comprises more than just usage, as participants may review or complete the full intervention without really interacting or engaging. Engagement requires a qualitative assessment of the participant experience in addition to or in place of objective measures of usage, such that it not always easy to evaluate.

2.5 Usage metrics

Usage metrics that can be gathered to measure participants' usage of a web-based intervention are numerous. Table 1 provides explanations of some commonly used metrics. A participant can interact with the intervention website on different levels and usage metrics help to get an insight of how participants use the intervention (39). Participant summary measures can be derived from these metrics, for example a participant's average page view

duration or an average time spent on site. Tracking usage of the individual components of an intervention (for example, modules, lessons and sessions) is useful to provide insight into the usage of each component type. The term “session” in this field usually refers to a content component of an intervention that is similar to a module or a lesson. However, “session” in technical terms refers to a “single log in or the amount of times a specific activity is accessed” (40)).

Table 1. Glossary of terms for collecting usage data

Usage metric	**Description/Example**
Browser Type	Type of browser used such as “Google Chrome”, “Firefox”, “Microsoft Edge”.
Click/Link	A single instance of a participant following a hyperlink from one page in an intervention website to another.
Device	Type of device such as desktop, tablet, mobile.
Frequency	How often participants access an intervention website in a given time period.
Geographical Location (Geolocation)	Where in the world the client computer is located (or the ISP that the client connects to). This is determined by looking up the physical location of the IP address using a lookup service such as https://www.iplocation.net/.
Hit	A request for a resource from the webserver.
IP Address	The network (Internet Protocol) address (41) of the computer/device accessing the website, e.g. 127.0.0.1
Login	Signing in, using credentials to gain access to the intervention website.
Module/session/lesson	Interactive components of an intervention website. Example of other such components can include exercises, assignments or similar that represent the individual components.
Page Name	The name of the intervention website/URL being accessed.
Page View	The request for a website.
Pathway	The chronological sequence of pages that a participant accessed in a specific session or visit.
Session Duration (technical)	Average amount of time that participant spend on the intervention website each time they visit. It is calculated as the sum total of the duration of all the sessions divided by the total number of sessions.
Time spent on site	The time that a participant (individually) or participants spend online on the intervention website.
Timestamps	A sequence of characters containing information about the time a certain activity has occurred. Timestamps can be used to calculate time spent on site.

Usage metric	Description/Example
Unique Client	The uniquely identified client generating page views within a specific time period. The unique client is often a combination of computer and browser.
User ID	A unique identifier for the participant accessing the page, this could be derived from a unique URL or information obtained when a participant logs in to the intervention website.
Video usage	Number of videos viewed, length of videos viewed, which video has been watched if multiple videos on website, YouTube videos viewed.
Visit / Session	The series of pages that the same uniquely identified client has requested within a defined time period.
Web-based games	Games on the website, such as those which are interactive or educational.

2.6 Reporting usage in RCTs of web-based interventions

Usage data are becoming increasingly important, in order to analyse how much the intervention is being used by trial participants and to link the effectiveness of the web intervention with the actual usage of the intervention. Knowing how and to what extent a user uses a web-based intervention can eventually provide valuable information not only on how much the web-based intervention was utilised but also can assist into understanding the efficacy of the each. In order to allow analysis of web usage data in RCTs, information on usage should be reported by trialists. With the increasing complexity and design of clinical trials, it has become clear that extensions to the original CONSORT statement would be required to provide increased clarity of reporting across these new designs, interventions and data sets. To address the specific challenges of web, mobile, and 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 (7, 42). The CONSORT-EHEALTH guideline encourages trialists to report engagement and usage; in subitem 6a-ii, it suggests that “researchers explain how use and engagement was measured and defined” and in subitem 7-I it asks that “use and usage outcomes should be reported” (42).

2.7 Tracking methods for collecting usage data

Usage metrics can be captured using various automated tracking methods (tools) (43). Tracking methods have been developed throughout the years and have been adapted to be used in this field and in scientific research. They can be split into two categories, either client (browser) based or server based. Client based methods, such as Google Analytics (GA) (44), rely on the web browser supporting them (e.g. JavaScript (JS) (45) being enabled) (46, 47) whilst server based methods such as web-server log data (48) will always be populated, as they record what data are sent to the client. The term GA covers all of the tracking and analytics tools available from Google to track users' activities on web sites. Client based methods also include JS trackers such as Open Web Analytics (49), Matomo (formerly known as Piwik) (50), Amplitude (51) and others.

To allow trialists to receive accurate information about participants' usage, it is important to determine the accuracy of the tracking methods used. Data from different tracking methods can be compared and these data may not always match completely. For example, reports on certain usage metrics between GA and Matomo have a potential to differ by between 5% and 10% (52). The basic concept in all tracking methods is the same but they may not report the same tracking data, as they differ in the way they track, report, and analyse data. Some of these methods, such as GA, were not originally designed for accurate reporting of usage but have been adopted by researchers to measure usage.

To link intervention usage to a particular participant, rather than just obtaining general information about overall intervention usage by all participants, each participant requires a unique identifier (UID), such as the study randomisation number, username or an IP address (53). The use of a UID facilitates linking intervention usage with outcome data on an individual participant basis. Such data are important for trialists to gather these data as information on aggregated data cannot provide enough detailed information.

The tracking methods, usage metrics and the terms described above are explored in more depth in context of web-based interventions in the following chapters.

3. Systematic review of web-based interventions in randomised controlled trials

3.1 Introduction

This chapter describes the methods and results of a systematic review (SR) of web-based interventions in RCTs. This review aimed to determine the extent of web-based intervention use in RCTs, to assess the characteristics of web-based interventions in RCTs and ascertain current practice among online intervention RCTs in terms of collecting, reporting and analysing of web usage data. Information was extracted on methods for gathering usage data currently used in existing web-based intervention RCTs, whether trialists checked on the reliability of their methods, and whether they prescribed an "online dose" meaning that participants were told ("prescribed") how to use the web-based intervention and how often. Reports on patterns and levels of usage were explored, as well as whether specific adjustment was made for intervention usage for any outcomes in the analysis.

3.2 Previous systematic reviews of web-based interventions

A SR is a research method used in many disciplines, designed to answer a specified research question and provide a comprehensive summary of the outcomes of research (54-56). This method has been widely adopted for research in RCTs. Conducting a SR is often an important stage when planning to apply for funding for an RCT, as the SR will determine whether the research question of interest can already be answered from existing data available from studies that have already been carried out. A SR involves searching for and combining information from all studies that can be accessed relating to a given clinical research question (57).

SRs are carried out to provide greater insight in health research. These reviews follow strict methodology, including predetermined search strategies for the selection of studies (54) with carefully chosen search terms. Prior to publishing a SR, a protocol for the review is essential to ensure transparency, rigorous conduct and evidence of thoroughly planned work.

The first phase of this research was a search to determine if the review question had been investigated recently. An initial search of PubMed (58) was completed to ascertain whether there had been any SRs of web-based intervention trials published to date (see Table 2 for search terms). The search terms were chosen with a PubMed librarian (59) to ensure all relevant studies would be included.

Table 2. Search for published systematic reviews of web-based intervention trials

(online[tiab] OR digital[tiab] OR web-based OR web) AND internet[majr] AND
("Systematic Review"[Publication Type] OR "Systematic Reviews as Topic"[Mesh])
(PLUS manual entry of upper limit of 31/12/2017 for date published)

To be eligible the study needed to be a SR of a web-based intervention in any clinical specialty, written in English and published by the end of 31/12/2017.

The PubMed search for SRs 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, 32.5%) as shown on Table 3. These SRs focused

on topics such as outcomes, successful interventions, comparison of web-based interventions vs face-to-face interventions, why these interventions are delivered through Internet or examining whether these interventions cause more harm than good (8, 60-64). None of these SRs included a comprehensive search of all published online health intervention trials, rather they concentrated on individual clinical specialties.

Table 3. Clinical or methodological areas covered by systematic reviews identified in search

Clinical area	Number (% of 123 systematic reviews)
Breastfeeding	1 (0.8)
Cancer	4 (3.3)
Cardiovascular	4 (3.3)
Caregivers	1 (0.8)
Chronic health conditions	1 (0.8)
Cyberbullying	1 (0.8)
Dentistry	1 (0.8)
Diabetes	8 (6.5)
HIV	3 (2.4)
Health promotion[1]	47 (38.2)
Physical activity	12 (9.8)
Weight	10 (8.1)
Diet	10 (8.1)
Alcohol	7 (5.7)
Smoking cessation	6 (4.9)
Lifestyle/health behaviours	6 (4.9)
Sexual health	3 (2.4)
Gambling	1 (0.8)
Social	1 (0.8)
Insomnia	1 (0.8)
Health information	1 (0.8)
Networking	1 (0.8)
Mental Health	40 (32.5)
Meta-analyses	1 (0.8)
Neurology	1 (0.8)
Pain	3 (2.4)
Phalloplasty	1 (0.8)
Respiratory	1 (0.8)
e-trials	1 (0.8)
e-health definitions	1 (0.8)

[1] Note that 5 reviews covered 2 health promotion areas and 2 reviews covered 3 health promotion areas.

3.3 Aims and objectives

This SR 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. The SR also assessed the study characteristics of these trials, including the types of design, intervention format and clinical areas.

The review addressed the following questions:

1) How many RCTs utilising web-based interventions have been published up to the end of 2017?

2) What are the characteristics of the RCTs?

3) On average, how many of those RCTs collect, report and analyse web usage data?

4) What methods do trialists use to ascertain trial participants' usage with web-based interventions?

5) What statistical methods are used to account for intervention usage in outcome analyses?

3.4 Methods

After the initial systematic search of PubMed to ascertain whether there had been any SRs of web-based intervention trials published to date, the electronic database PubMed was then searched to identify all RCTs of web-based intervention trials published by the end of 2017 (see Table 4 for search terms). The protocol for the SR was developed according to the International Prospective Register of SRs (PROSPERO) (65), the registration number is CRD42018095116 (66).

3.4.1 Selection criteria

To be included in the SR studies had to meet the following inclusion criteria:

- A RCT
- Involving a web-based intervention
- Indexed in PubMed up to the end of 2017.

Reports that met the following exclusion criteria were not considered for this review:

- RCTs that did not involve a web-based intervention
- Non-randomised studies (e.g. feasibility studies that does not involve randomisation, observational studies, quasi-randomised studies, surveys, lessons from previous studies, questionnaire analyses, educational studies)
- Secondary analysis studies
- RCT protocols
- SRs

3.4.2 Search term

The search terms for the SR were developed with a PubMed librarian (67) same as with the systematic search to ensure that all relevant studies will be included. The following search term was used:

Table 4. Search 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)

3.4.3 Selection of eligible publications

Duplicate records were removed, and all abstracts identified through the PubMed search were read by in order to assess eligibility of each study according to the inclusion/exclusion criteria. Where there was any uncertainty regarding eligibility, supervisors were consulted and any disagreements were resolved by consensus. The eligibility of 5% (77) of the abstracts were randomly selected and reviewed by my supervisors to validate this process, on which there was 100% agreement.

Due to the number of publications returned (n= 1726) it was decided to base this SR on a representative sample of publications. One hundred studies were randomly selected from the cohort of eligible RCTs identified in this search, with sampling proportional to the annual distribution of publication years across the entire set of included studies as shown on Figure 3. Appendix 1 lists all of the studies included in the full review.

3.4.4 Data collection form

The initial data extraction form was piloted on five studies and refined accordingly with additional relevant questions added. The final dataset included the study characteristics; whether a CONSORT (68) flow diagram and a CONSORT-EHEALTH (42) 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 usage. Any uncertainty about the extracted data was resolved by discussion with supervisors. Appendix 2 lists the final data extraction form.

3.5 Results

3.5.1 Summary of search results

The electronic database search yielded 1726 studies meeting the required criteria (Figure 3). 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.

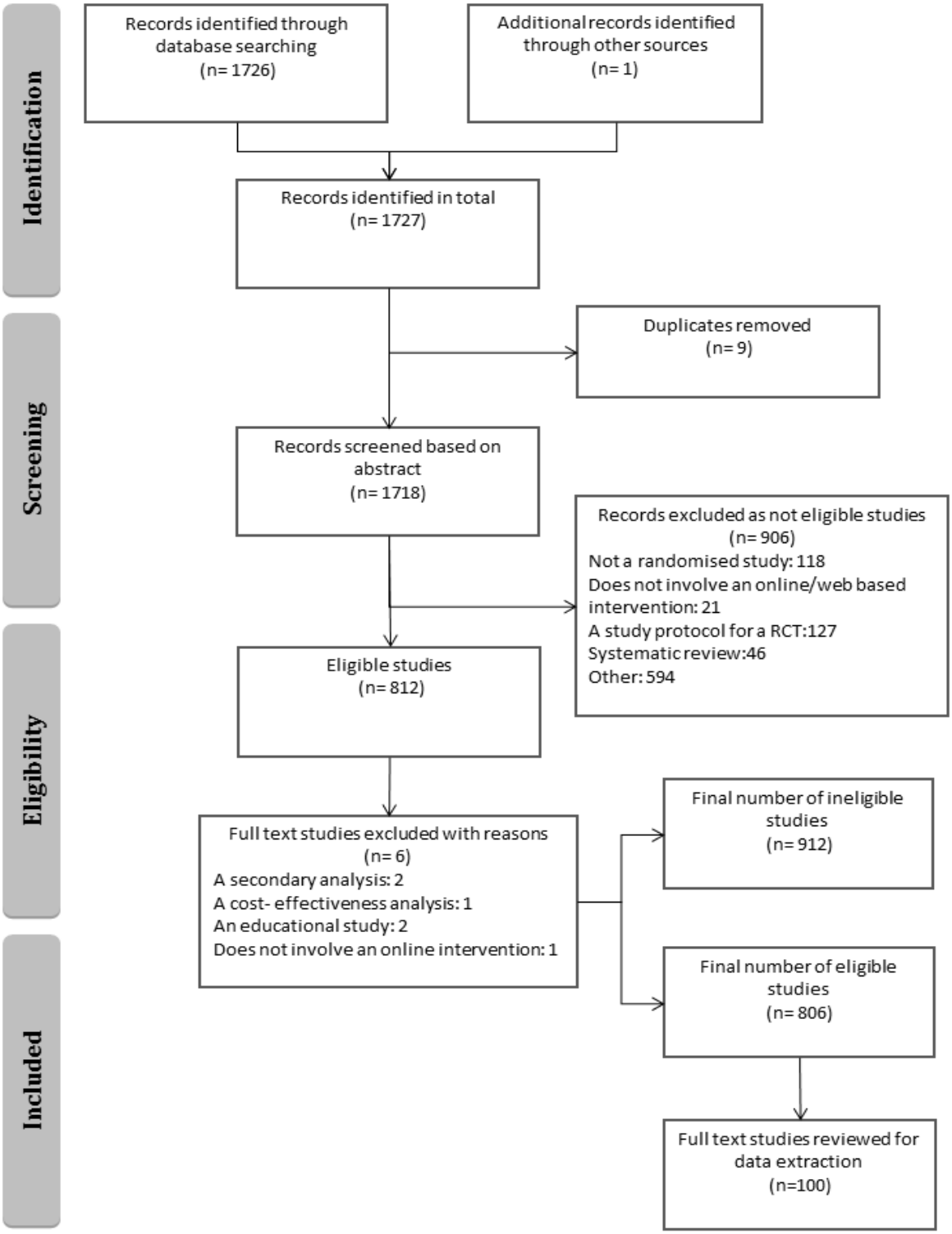


Figure 3. Flowchart describing the systematic literature review process

3.5.2 Published RCTs of web-based interventions

The number of RCTs using web-based interventions is displayed in Figure 4 demonstrating an increasing trend in the use of web-based interventions within RCTs with random fluctuation between successive years. However, despite this increase, the number of RCTs utilising web-based interventions remains proportionally low when compared to the total number of RCTs during this period (estimated as 496,238 from a PubMed search on 26/03/2019). 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) and a PubMed librarian confirmed that new publications can be posted on PubMed later than their publication date (59).

The slight drop in 2014 likely to be a random fluctuation rather than anything related to the registration life cycle.

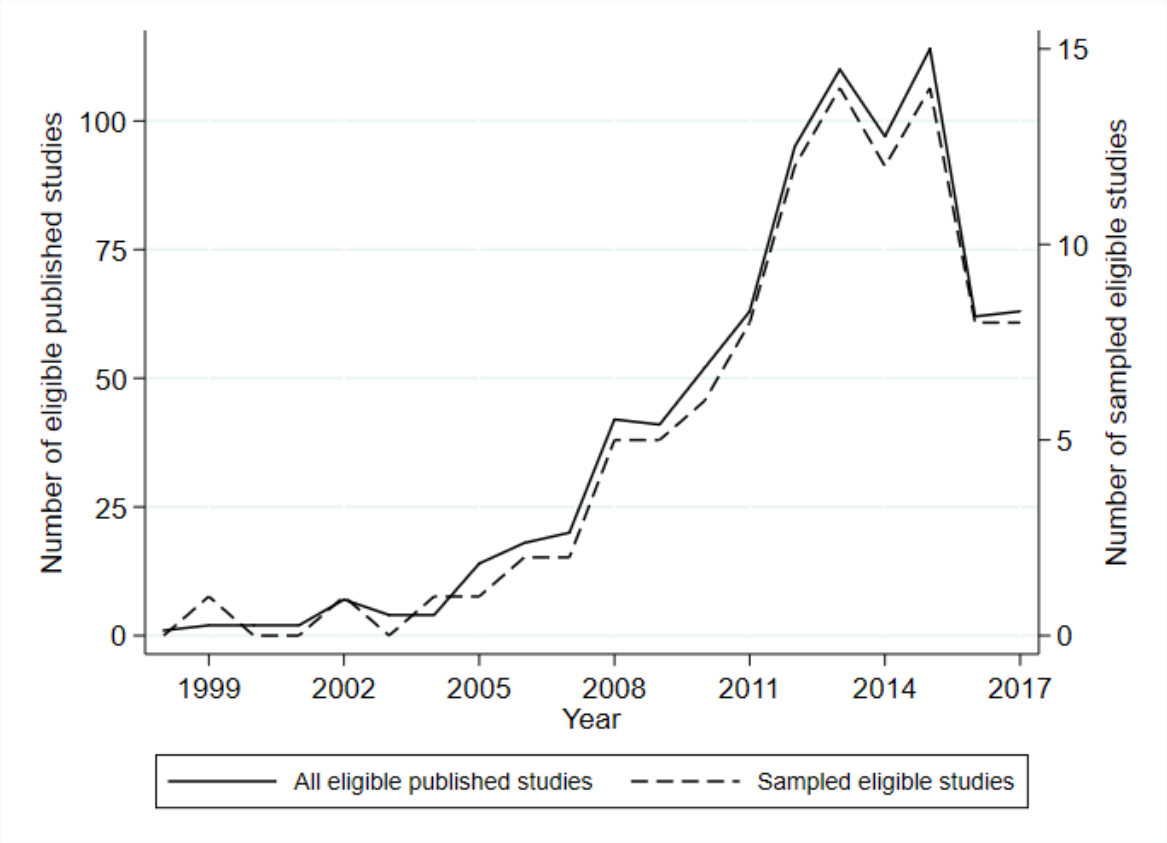


Figure 4. Distribution of RCTs utilising web-based interventions each year

3.5.3 Description of studies and study characteristics

As can be seen from Table 5 most of these studies covered health promotion (42%, most commonly smoking cessation, physical activity and weight) and mental health (32%).

Table 5. Clinical or methodological areas identified in studies

Clinical area	
Health Promotion	42
Weight	7
Physical activity	8
Alcohol	3
Eating disorder	3
Tanning	1
Lifestyle behaviours	2
Smoking cessation	11
General health management	1
Diet	2
Sexual Health	1
Physical activity and diet	2
Adolescent health	1
Mental Health	32
Cancer	4
Respiratory Illnesses	3
Neurology	3
Diabetes	3
Other	13
Dentistry	2
Pain	1
Otolaryngology	2
Autonomic Arousal	1
Discharge from Emergency Department	1
Cardiovascular	2
Parathyroid disorder	1
HIV	1
Cancer screening	1
Women's Health	1

Characteristics of the 100 publications randomly selected for data extraction are given in Table 6.

Table 6. Description of studies and study characteristics

Design	
Superiority	98
Equivalence	2
Blinding	
Not stated	40
None	46
Single	13
Double	1
Web-based intervention	
Website	77
Website plus additional element	10
Internet (Other)	13
Control arm	
Not stated	3
No intervention	9
Non Internet intervention	28
Waiting list group	32
Website	14
Internet (other)	14
Intervention instructions	
Email instructions alone	24
Face to face instructions alone	13
Online/website information	8
Combined instructions	15
Other	5
Not stated	35
CONSORT flow diagram presented[2]	79
CONSORT E-HEALTH guidelines[3]	26 (38.2)
Amount of missing primary outcome data reported	87
Mean (SD)	25.7 (18.6)
Range	(0,81)

The vast majority of RCTs had a superiority design and did not use blinding (which refers to the lack of knowledge relating to the treatment to which participants are assigned (69)), 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 clinicians) and only one

[2] Denominator is equal to 100, as all trials were published after the original CONSORT flow diagram (1996).
[3] Denominator is equal to the number of trials published since CONSORT-EHEALTH (2011) (n=68).

study reported being double-blind (patients and assessors). In the 86 trials that 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.

The majority of studies involved a website as the intervention. Other interventions included: a podcast; E-mails; Internet video conference; web applications; web video camera; computer simulation; computer generated photo aging intervention; web-message boards; Internet partner (exercising with an 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). Control arm web-based interventions were in the form of a website or other type of web-based interventions.

Table 7 displays the crosstabulation of web-based and control interventions in the 100 sampled trials.

Table 7. Cross-tabulation of randomised arms

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

Trialists used various formats to present instructions to guide the participants on how to use the web-based intervention (Figure 5). They relied on email, face-to-face, online/website information, combined instructions or other type of instructions (sealed envelopes, phone calls, printed instructions, mailed instructions). The rationale for their choice of instruction format was not explained by any of the trialists.

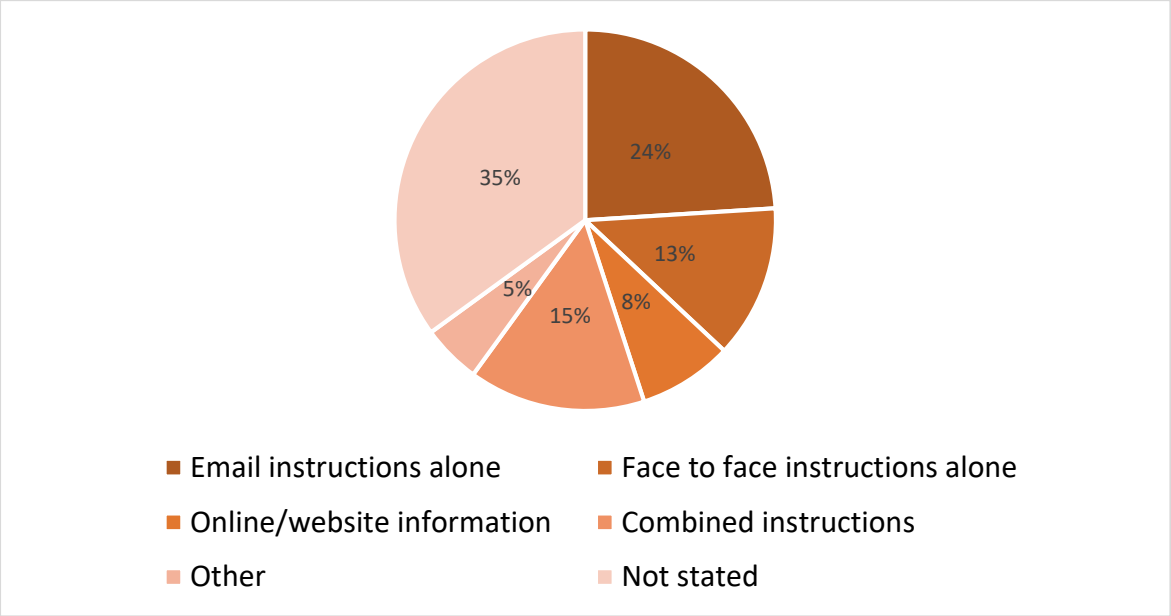


Figure 5. Intervention instructions

Table 8 gives further details about the type of combined instructions.

Table 8. Combined instructions

Combined instructions	15
Email + online/website information	1
Email + phone calls	1
F2F + printed instructions	6
F2F + printed instructions + optional phone instructions	1
F2F + email	3
F2F + instructional video	1
F2F + online/website information	1
Phone calls + mail	1

By assessing their characteristics further, information was extracted on whether trialists were including a CONSORT flow diagram and a CONSORT-EHEALTH checklist and how many of those reported collection of web usage.

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 9). Sixty (88.2%) of these 68 studies collected web usage data as shown in Figure 6.

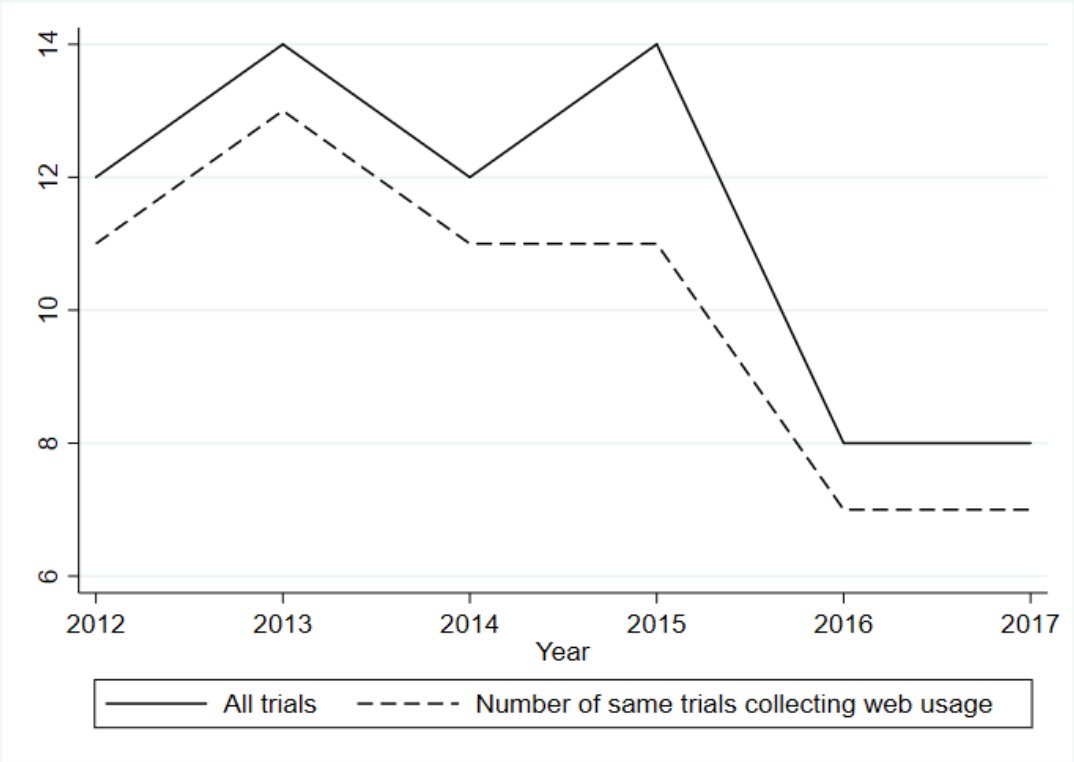


Figure 6. RCTs of web-based interventions published after CONSORT-EHEALTH (total and number that collected web usage)

Table 9 summarises the rates of web usage data reporting in RCTs before and after the publication of CONSORT-EHEALTH (2011). The publication of CONSORT-EHEALTH does not appear to have positively influenced the rate of reporting web usage. Among those RCTs published after CONSORT-EHEALTH, those that included CONSORT-EHEALTH checklist had a lower rate of reporting web usage (84.6%) than those that did not include a checklist (90.5%). However, this difference is not statistically significant at the 5% significance level as the p-

value using the Pearson's chi-squared test is 0.466. Before 2011 the rate of reporting web usage data was even higher (93.8%) with 30 out of 32 RCTs recording web usage.

Table 9. Rates of reporting web usage data according to publication year and CONSORT-EHEALTH checklist reporting

Publication year			**Reported web usage data**		**Total**
			Yes	No	
≤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

Figure 7 shows comparison between RCTs reporting CONSORT-EHEALTH checklist versus same RCTs, which also reported about collecting web usage. 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).

In this SR 87 of the sampled studies reported attrition rates. The mean overall attrition rate from the RCTs was 25.7%. The mean attrition rate for the intervention group was slightly higher than the control group. Of the 87 RCTs that reported attrition rates, two studies reported having no attrition at all (70, 71).

Table 10 gives further details on amount of missing primary data reported for the intervention and control groups.

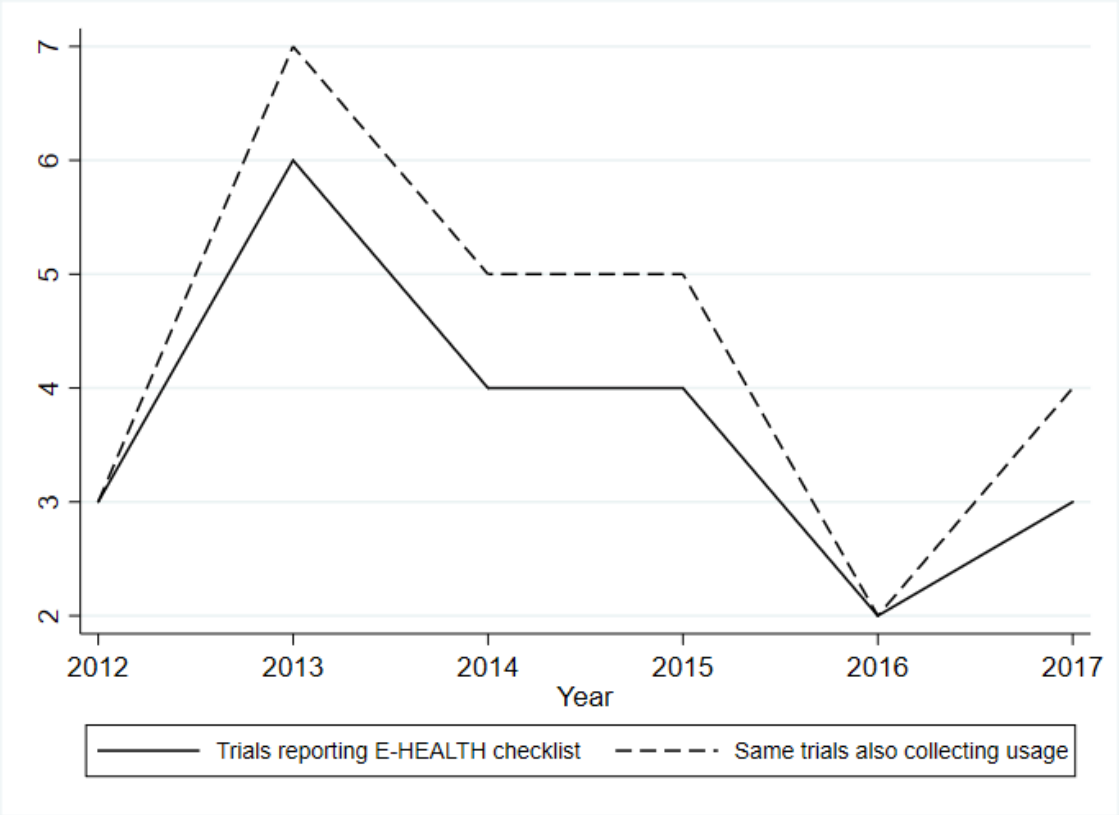


Figure 7. RCTs reporting E-HEALTH checklist vs RCTs reporting E-HEALTH checklist and collecting web usage

Table 10. Percentage of missing primary outcome data reported in 87 studies

Percentage of missing primary outcome data reported	
Intervention group	
Mean (SD)	28.8 (20.7)
Median	27.5
IQR	(13.5,47.2)
Range	(0,73.5)
Control group	
Mean (SD)	23.3 (18.0)
Median	11.2
IQR	(8.8,37.6)
Range	(0,70.1)

3.5.4 Collection and reporting of web usage data

Table 11 shows results of collecting and reporting of the reported web usage data from the studies.

Table 11. Summary of collecting and reporting web usage data

	Number (=% of 100 studies)
Web usage collected	
No	10
Yes	90
Unique Identifier	51
Implied but not specified	7
No	3
Not stated	29
Performed check on reliability of methods	
Multiple methods	2
Single method	2
Online intervention changes reported	
Online intervention prematurely terminated	29
Online intervention switches to alternative arm	2
Online intervention switches to non-online non-trial intervention	2
No	67

Web usage was collected in 90 of the studies, but more than half (49, 54%) of these studies did not state the method used for recording the usage. The most commonly reported methods used for tracking usage were logs, mainly server logs who were used eight times alone and once along another method (Figure 8). Other methods included website tracking data, GA, self-reported data and various other tracking methods. A clarification for the term of website tracking data needs to be addressed. Findings in the systematic review show that the trialists referred to the term “website tracking data”. In the interviews in the TRACK study in Chapter 4 website tracking data was referred to as a website platform feature to describe the method used for obtaining website tracking data. As the SR was published before the TRACK study the term “website tracking data” will remain throughout this chapter.

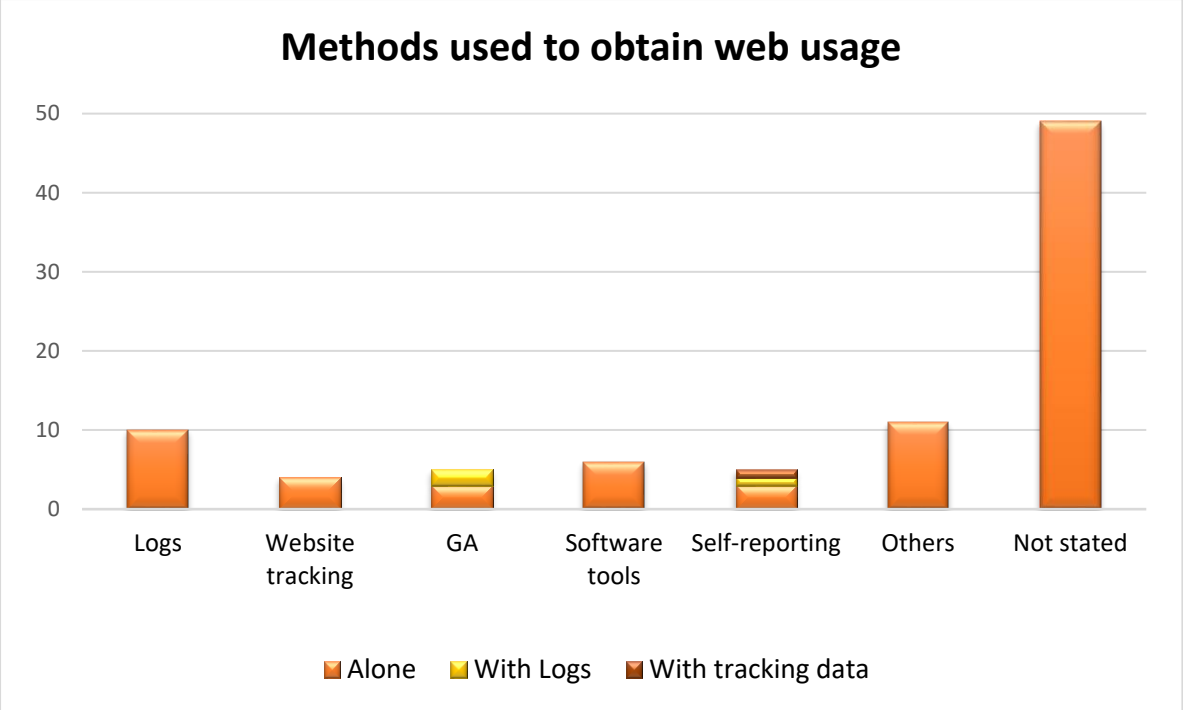


Figure 8. Web usage data collection methods among 90 trials which collected web usage data

Only four of 90 trial reports mentioned checking the reliability of their usage tracking methods, two of which used more than two tracking methods to capture and compare usage data.

Among the 87 trials involving a website, 78 (90%) recorded usage metrics, most commonly in terms of logins (27,31%), modules (14, 16%) and time spent on site (13, 13.9%) (see Table 12). Twenty-one (24.1%) of these trials recorded a combination of two usage metrics, most commonly logins plus an additional metric (13, 14.9%). Four trials (4.6%) recorded combination of three usage metrics (logins, time spent on site and modules; logins, time spent on site and page views, logins, time spent on site and visits; visits, page views and timestamps).

Among the 13 trials involving an online intervention other than a website, 12 (92.3%) recorded usage, most commonly sessions (2, 15.4%) and video usage (2, 15.4%) (Table 13). Two (15.4%) of these trials recorded more than one usage metric (sessions and time spent on site and logins and visits).

Table 12. Web usage metrics recorded among trials which involved a website

	Number of trials (% out of 87 trials[4])
No web usage data collected	9 (10.3)
Logins	27 (31%)
Modules	14 (16%)
Time spent on site	13 (14.9%)
Visits	9 (10.3%)
Sessions	8 (9.2%)
Page views	8 (9.2%)
Clicks	5(5.7%)
Timestamps	3 (3.4%)
Others	16 (18.4%)

Table 13. Web usage metrics recorded among trials which involved a web-based intervention other than a website

	Number of trials (% out of 13 trials[5])
No web usage data collected	1 (7.7%)
Sessions	2 (15.4%)
Video usage	2 (15.4%)
Time spent on site	1 (7.7%)
Logins	1 (7.7%)
Visits	1 (7.7%)
Page views	1 (7.7%)
Others	6 (46.1%)

Forty (44%) of the 90 trials that collected web usage reported using UID, most commonly login credentials or IP addresses (see Table 14). 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.

[4] Note that 21 trials included two metrics of usage and four trials included three metrics of usage.
[5] Note that two trials included two metrics of usage.

Table 14. Unique identifiers reported

	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 (receiving face-to-face therapy).

3.5.5 Intervention dose

Sixty-nine of our sample studies 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 35 (50.7%) of these 69 studies (mean, SD = 2.8, 2.3; range = 1, 14).

Duration of the "prescribed" online dose was not reported in 46 studies meaning that the dose was specified in terms of number of sessions, modules, assignments but without giving specific time frame for completion of these tasks. 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.

In relation to the total intervention dose, 24 studies estimated the total usage participation of between 10 to 1260 minutes.

3.5.6 Analyses involving usage and statistical methods to account for web usage in outcome analyses

Table 15 describes the trial analysis sets and analyses involving usage.

Table 15. Analysis set and statistical methods of usage analyses

	Number (=% of 100 studies)
Analysis set	
ITT alone	44
PP (including completer analysis)[6]	4
ITT and other analysis	12
ITT and PP (including completer analysis) [7]	11
ITT and responder only analysis	1
Unspecified	40
Any analysis involving usage	35
Comparison of web usage between randomised arms	3
Assessed patterns of web usage	4
Correlation between web usage and outcome	9
Completer analysis	11
Regression analyses with intervention use as a covariate	6
Causal analysis (CACE)	2

Of the 60 RCTs that defined analysis populations, 44 reported using ITT population alone and 12 used ITT alongside other analysis populations (10 ITT/PP combinations, one ITT/Completer analysis and one modified ITT/responder only analysis (responder analysis based on completing follow up)).

Only 35 (39%) of the 90 trials which collected web usage data investigated levels of usage (Table 15). Nine RCTs made correlation between web usage and outcome; Lundgren et al (72) stated that the number of logins to the web-based intervention correlated significantly with improvement in depressive symptoms. Three RCTs made comparison of web usage between randomised arms. Alley et al (73) compared intervention website usage between intervention groups and Kukafka et al (74) looked at differences between randomised arms with respect to the frequency of system (web-based intervention) use. Four RCTs assessed patterns of web usage only. In Ramadas et al (75), trial usage to the intervention was assessed by the number

[6] One trial was labeled as PP and wasn't categorized as such by the authors.

[7] Five RCTs didn't specifically state the analysis as "PP" but were categorised as such, due to the inclusion of a "completers" analysis, with "completer" defined in terms of engagement with the intervention.

of logins and duration spent in minutes on the website. They reported that acceptability measures were moderately correlated with the intervention usage metrics. Bowen et al (76) and Fleischer et al (77) examined website usage data to assess patterns and frequency of use; in addition, Fleischer et al (77) examined differences between participants who did and did not use the intervention website. Meischke et al (78) examined patterns of usage and made comparison between those who were and were not categorised as super-engagers.

To adjust for non- usage for any outcomes, 19 (21%) used statistical methods such as completer analysis (11 RCTs), regression analyses with intervention use as a covariate (six RCTs) and CACE (two RCTs). 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.

3.6 Strengths and limitations of the systematic review

To the best of the author's knowledge this is the first SR to investigate the extent and nature of web-based interventions in clinical trials and the current practice among trialists in terms of collecting, reporting and analysing usage data. This SR investigated the characteristics of the web-based interventions and the methods used to measure, report and analyse usage. The SR included all web-based interventions without focusing in one area in particular.

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

Only 100 of the eligible trial publications were included in the data extraction exercise. Due to the high number of eligible trials 812 the sample size needed to be limited and this number was considered sufficient to give reliable estimates and an accurate indication of trends in reporting and analysis. There is no sample size calculation for this number but it represents a sufficiently large sample to provide precision in the results without demanding too much work.

The process of determining eligibility of web-based intervention trials was based on the review of abstracts only; therefore, some ineligible studies were initially included but later identified; as evidenced by the exclusion of six of the studies from the sample of 100 studies.

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, the total of 806 trials cannot be taken as the absolute number of web-based intervention trials published up to the end of 2017.

3.7 Discussion

In order to increase the knowledge of participants' usage in RCTs it is important to know how many reports of RCTs of web-based interventions in all clinical areas have been published, what characterises them and how many of them collect and analyse usage information.

Although the use of web-based interventions in RCTs has increased over the last 15 years, the number is still relatively 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 SRs 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 SRs identified were restricted to trials within a certain clinical condition, other than the review by Mathieu et al (8), 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 (62) reviewed trials which defined "eHealth". As such, this review of SRs demonstrated that there were no previously published reviews of all web-based intervention studies, providing evidence of the novelty and usefulness of the present SR study.

By assessing their characteristics, it can be noted that the vast majority of sampled RCTs were designed as superiority trials and either did not use blinding or did not state whether there was any blinding. In trials of web-based interventions, blinding can be more challenging than in standard interventions. Blinding in web-based interventions can be done if participants of the control group are allocated to an existing web-based intervention for example a standard website (8). Participants in the intervention group will then have access to an upgraded

website with interactive features (8) and are not going to be familiar with the standard website. Blinding is optimal whenever possible to avoid risk of bias due to expectations associated with intervention (79, 80) but only 13 of the 100 RCTs reported blinding.

The trial web-based interventions included in the sampled studies usually took the form of a website (77%); an additional 10 studies used a website in combination with an additional element and 13 studies used other web-based intervention, namely: mobile app; web-based message boards; emails; Internet video conference; web application; web video camera; computer simulation; computer generated photo aging intervention; and an Internet partner. Although it was decided that the scope of this SR would not extend specifically to include mobile apps (and therefore this term was not included in the search strategy), the search did identify one such RCT.

Good quality reporting allows clinicians and researchers to replicate trial methods (81) and supports understanding of the trial methods, interventions and outcomes. This SR 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 (82).

The CONSORT-EHEALTH guideline recommends reporting data collection methods and results relating to usage, 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; however, this observation is based on a relatively small number of trials and the difference observed is not statistically significant.

Results from this SR show that in terms of giving intervention instructions to participants on how to use the online intervention, trialists use various types of instructions; participants can receive instructions in the form of emails, face-to-face, online/website information, or a combination of various instructions. There was no indication on what was the most appropriate and efficient way was of delivering instructions or if any type was preferred by participants.

Generally, trialists in these studies did report attrition, with 87 of them reporting these rates and one RCT providing an explanation on why there were unable to capture attrition rates.

Seventy-nine RCTs reported a CONSORT diagram; there were eight additional RCTs which did not include CONSORT diagram but still reported attrition rates.

One third of the studies reported online intervention changes. Examples of such changes included premature discontinuation of the treatment, failure to activate account or log in, not downloading the intervention or login failures.

Unlike drug interventions, the adherence to which can be summarised using uncomplicated measures of treatment intake (for example, initiation, completion and persistence (82)), web-based interventions often involve multiple features, usage and engagement with which may be more complex to record. This review demonstrated that trialists collect data on a wide variety of web usage metrics, most commonly logins, modules and sessions (intervention components) and time spent on site. Almost one third of the trials (27/90, 30%) which recorded web usage information collected usage data on more than one metric, the most common combination being logins and time spent on site. The likelihood of web usage being measured did not vary according to whether participants were recommended to follow a specific dose: the proportion of trials that measured usage was equal to 90% in those trials which did, and in those which did not, specify a recommended dose. Participants were 'prescribed' certain interactive components (sessions, modules, lessons) to complete in a certain amount of time in 69 trials. Among those RCTs that reported a duration associated with the web-based intervention, most ranged from 1-12 weeks.

Out of 90 studies collecting web usage, 49 (54%) studies did not mention the tracking method used to ascertain trial participants' web usage. The most common methods reported to record web usage data included logs (predominantly server logs), website tracking data, GA and self-report 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. This is going to be examined in Chapter 5 which reports results from an evaluation of different tracking methods. Assessing reliability of usage data collection methods is therefore vital, but very few trialists in our sample mentioned checking the reliability of their usage measurement methods. Accuracy of methods for collection web usage data was rarely explored in the 100 sampled studies with only 4 (4.4%) of 90 RCTs reporting about reliability. Van Rosmalen-Nooijens et al (83)

compared results from GA, content management system logs (CMS) and data files with self-reported data from participants and concluded that the actual usage information from the different sources corresponded well. Fleisher et al (77) found discrepancies in self-reported data and actual usage data obtained from the NetTracker software tool. Nguyen et al (84) and Mermelstein et al (85) 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.

Trialists rarely provided a rationale for their choice of web usage metrics or analysis methods to adjust for web usage. Of the 90 RCTs that collected web usage data, only one third of trialists investigated patterns of web usage. Half of these explored patterns of usage in the form of comparison of web usage between randomised arms, assessing patterns of web usage only, or correlation between usage and outcome.

Only two of the 15 trials which adjusted their outcomes for usage levels used 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' usage on their outcomes.

4. Investigating trial teams' experiences of using tracking methods for web-based interventions: A mixed methods study

4.1 Introduction

The systematic review (86) described in Chapter 3 showed that there is an increasing trend in the use of web-based interventions in RCTs. Although the majority of studies reported collecting details on web usage, more than half did not state the tracking method used, or did not provide the level of detail expected from the CONSORT-EHEALTH guideline on reporting web usage data and collection methods. This finding highlighted the need to conduct a mixed methods study (the TRACK study), combining interviews and an online survey to investigate trial teams' experiences of using tracking methods for web-based interventions including: the reasons for choosing a particular method; ease of implementation and use; and the costs associated with the use of different tracking methods. Such information may be beneficial for other trialists when deciding which tracking method would be the most appropriate for tracking participants' usage with web-based interventions.

4.2 Aims and objectives

The aim of the TRACK study was to explore trialists' experiences of implementing tracking methods to determine usage in trials of web-based interventions.

The objectives of this study were to review and explore:

1. reasons for choosing a particular tracking method, what influenced this decision, and how it was decided;
2. ease of implementation of the tracking method, whether developers' assistance was needed for setup, the timescale of the implementation process, and any obstacles that were experienced during the process;
3. experience of using the tracking method, whether the tracking method met or exceeded the trialists' expectations, whether the data obtained were sufficient for purpose and provided all information needed;
4. costs associated with the tracking method, including the costs of accessing the tracking method, implementation, extracting data and maintenance.

4.3 Methodology

The mixed methods design for the TRACK study combined qualitative semi-structured online interviews and an online survey.

Qualitative research focusses on the process of gathering, analysing and interpreting descriptive textual data (87-89). This method helps to understand and view data more thoroughly by putting the user in the focus (87-89). In clinical trials, qualitative insight enables an exploration of participant and trialists' experiences of an intervention, drug or a treatment (87, 88). It also helps to identify and address issues that can be difficult to explore using quantitative methods (87-89). Qualitative research has increasingly been recognised to have an important role in the field of clinical trials of health care, behavioural and public health interventions (90). Interviews are effective to provide in depth individual insight into given topic. They can help explore interviewees opinions, views, experiences and get better understanding on the research topic (91).

The surveys were added as an option if there was no response from participants to the interview request in order to maximise the insight gained. Survey can help gather data from

a geographically diverse population providing ease of access (92). Survey participants can also remain anonymous if they want to and they benefit from choosing a desirable completion time without needing to agree to a specific time with the interviewer (92). Because it was pivotal to gather individual experiences of using a particular tracking method it was decided for the TRACK study to combine these techniques.

In order to guide the development of study materials and analysis of data a phenomenological approach was chosen. Phenomenology is a philosophical approach to qualitative research that focuses on an individual's experience of a specific phenomena (93, 94). Phenomenology studies help to understand the meaning of people's lived experience of events or structures (94). As a researched methodology, phenomenology can be used when a study is exploring what a particular experience means to a group of people (94). Therefore, this approach was chosen to inform TRACK study methodology as it is aligned with the main aim of exploring trialists' individual experiences with their tracking methods. Phenomenology in health research can help trialists to learn from the experiences of others hence the experiences of trialists' use of tracking methods can help other trialists (95). Past experience can also influence which of the methods is used and, although using exactly the same method, trialists could have different experiences.

In traditional qualitative research it is not common to include quantitative results; however, this was felt to be appropriate for this particular study. Quantitative data were needed to convey a better understanding of the use of the tracking methods showing the number of methods used, usage metrics, advantages and disadvantages of methods, demographic details for trialists, and other important information to supplement the qualitative data.

Reflexivity in qualitative research enables researchers to examine their own judgment and reduce the degree to which personal opinions and knowledge has influenced the research (96, 97). This is required to maintain ethical decisions after gathering trialists led data from the interviews and surveys (97). The TRACK study contained certain technical details and the author's background is in computer science and software engineering. However, the development of the study and the coding framework was agreed with the supervisory team as part of the reflexive process and to ensure authors' views did not influence or bias interview/survey conduct, analysis and interpretation. Therefore, the author aimed to reduce the impact that her perspectives on tracking methods influenced how interviews were conducted and the interpretation of findings to draw data driven conclusions.

The interview topic guide and related survey questions were developed using findings from the systematic review, which demonstrated that the tracking method used was not stated in more than half of the trials; thus, it was decided to investigate this topic. So, the topic was developed to explore the tracking methods used in context of web-based interventions ensuring that enough information was gathered to provide detailed description of the use of the tracking methods, advantages and disadvantages, and main features. The initial proposed topic guide by the author was reviewed, amended and expanded after discussion with the supervisors.

Appendix 3 lists the survey questions and Appendix 4 the interview topic guide. Both the interviews and the survey aimed to address the same study aims and objectives.

4.3.1 Online versus face-to-face interviews

Eligible participants included international trialists involved in RCTs investigating web-based interventions. To maximise the potential sample and implications of findings, trialists were eligible from any country.

Due to the COVID-19 pandemic, interviews could only be made remotely (either online or by phone) rather than in person due to the infection control measures implemented by governments world-wide.

Research conducted online has advantages of involving participants world-wide and reaching a higher number of people (98, 99). Online research also benefits from being easier to arrange meetings and people did not need to travel.

However, face to face interviews benefit from having direct eye-contact in person with participants, which may be more comfortable for the participants and make easier for them to engage (or engage more timid participants). Also, face to face interview mean that participants do not need to have knowledge of online technology, install online platforms or have reliable wi-fi (99). Online interviews may be hampered by technical issues with wi-fi and communication platform installation. However, trialists involved in this type of research did have knowledge in creating web-based interventions, so they were comfortable using technology and no undesired issues were anticipated.

Another point was taking consent from participants which would have been easier in in-person communication rather than via email. However, this was adapted to the study and consent forms were obtained without any issues.

4.3.2 Ethical approval

Ethical approval was granted by the University of Liverpool, Health and Life Sciences Research Ethics Committee (Human participants, tissues and databases) review number 7981 on the 10/09/2020.

4.3.3 Inclusion/Exclusion criteria

Members of trial teams were eligible to participate if they had:

(1) knowledge of tracking web usage in web-based interventions as part of a RCT.

Exclusion criteria for this study were:

(1) members of trial teams who do not speak English;

(2) members of trial teams who were not aware of details relating to web usage tracking;

(3) trials in which usage was measured using participant self-reported data alone.

4.3.4 Recruitment and sampling

A search of RCT publications indexed in PubMed was conducted to identify eligible trials. The primary search of PubMed was supplemented with searches of the Journal of Medical Internet Research, Google Scholar and Scopus. The search terms are shown in Table 16.

Table 16. Search strategy of RCTs of web-based interventions

PubMed search	**JMIR search**	**Google Scholar/Scopus search**
(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 for data limit of 2015	randomized controlled trial of web-based online intervention	web-based AND intervention AND randomised AND controlled AND trial AND NOT protocol AND NOT systematic AND review

The reason for extending the PubMed search was to identify trials that had been published in 2020 and not yet been indexed in PubMed as well to include preprints. The search aimed to identify trials of web-based interventions published since 2015 that reported collecting web usage data. This study sought recently published trials to obtain more up to date information about tracking methods in use by trialists, given that tracking methods change rapidly over time. Eligible studies were identified, and the corresponding authors of these studies were contacted via email to ask if they or other members of the trial team had been involved and aware of details relating to tracking web usage. The contact details of eligible team members, such as the Chief Investigator (CI) or Information Systems (IS) person were requested when appropriate.

Participants were contacted via email invitation (Appendix 5) and sent the study Participant Information Sheet (PIS) (Appendix 6). Each potential participant was invited to take part in the interview. If they did not respond within two weeks, a reminder email (Appendix 7) was sent which included the option to take part in a survey if they were unable to take part in an interview.

The flow chart of the recruitment process is shown on Figure 9.

4.4 Interviews

4.4.1 Arranging interviews

Once eligible trials were identified the corresponding authors were contacted via email. If they responded to state that they were willing to participate, a suitable time and date was arranged for an interview and a calendar invitation was sent to the interviewee confirming the date, time and the platform. Trialists were given the option to have an interview via telephone, Zoom (100) or Microsoft TEAMS (101) platforms.

4.4.2 Informed consent

At the beginning of the interview, it was checked that the participant had had sufficient time to read the study PIS. If they had not, this document was read through with the participant. The aims of the study were explained, providing an opportunity for questions, and verbal informed consent for the study was obtained. This involved reading each aspect of the Participant Consent Form (Appendix 8) to participants, including consent for audio/video recording and receiving a copy of the findings at the end of the study. Each box on the consent form was ticked when the participant provided verbal consent. Informed consent discussions were video recorded for auditing purposes.

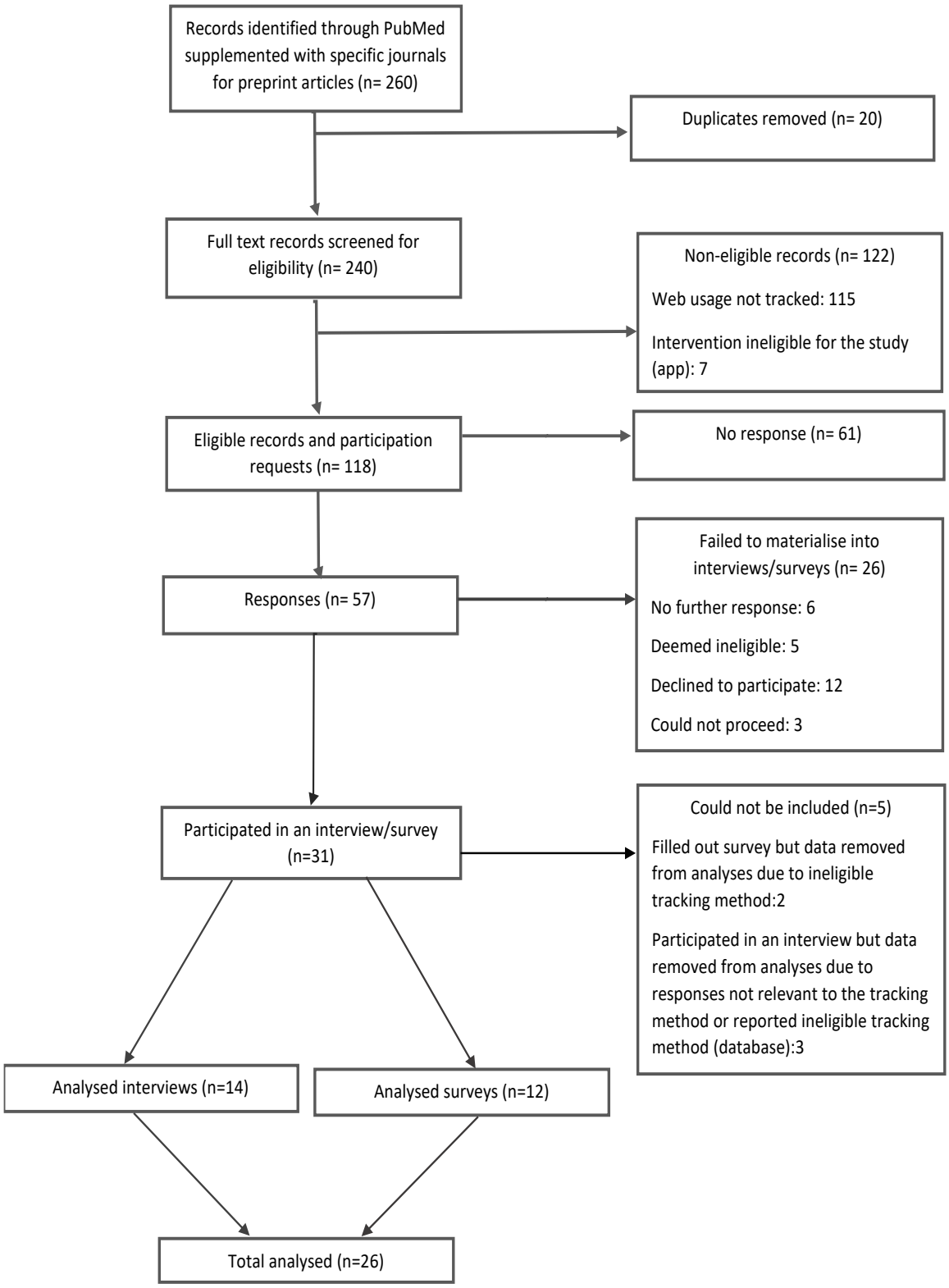


Figure 9. Recruitment process

4.4.3 Interview conduct

The interview commenced with the interview topic guide which explored:

- acceptability of the tracking method and the reasons for choosing it
- the implementation process of the tracking method, including trialists' views on the ease of the process
- the general use of the tracking method including any features that enhanced the positive experience or presented a problem for users
- the costs associated with the use of the tracking method

The study used an iterative approach whereby early findings or areas of questioning were added to the topic guide as the study progressed. After the interview was completed, the consent form was also signed by the author. The participant thank you letter and a copy of the consent form was then emailed to the participant. No incentives were provided to the participants.

4.5 Online survey

If potential participants did not respond to the email invitation a second follow up email was sent, which contained the option of completing a questionnaire instead of an interview. A link to the online survey questionnaire was provided in the email for completion. The online survey was conducted via JISC Online surveys program (formerly BOS) (102). Image of the JISC online surveys dashboard is shown on Figure 10.

At the beginning of the survey, a series of consent statements with check boxes were used to seek consent for participation. If participants did not tick all the mandatory boxes they were unable to proceed with the survey and a thank you message appeared on the screen.

The survey covered the same topics as the interviews. A combination of closed and open-ended questions was used. When the survey was complete, a message thanked participants for their time. Figure 11 shows the first three pages of the online survey.

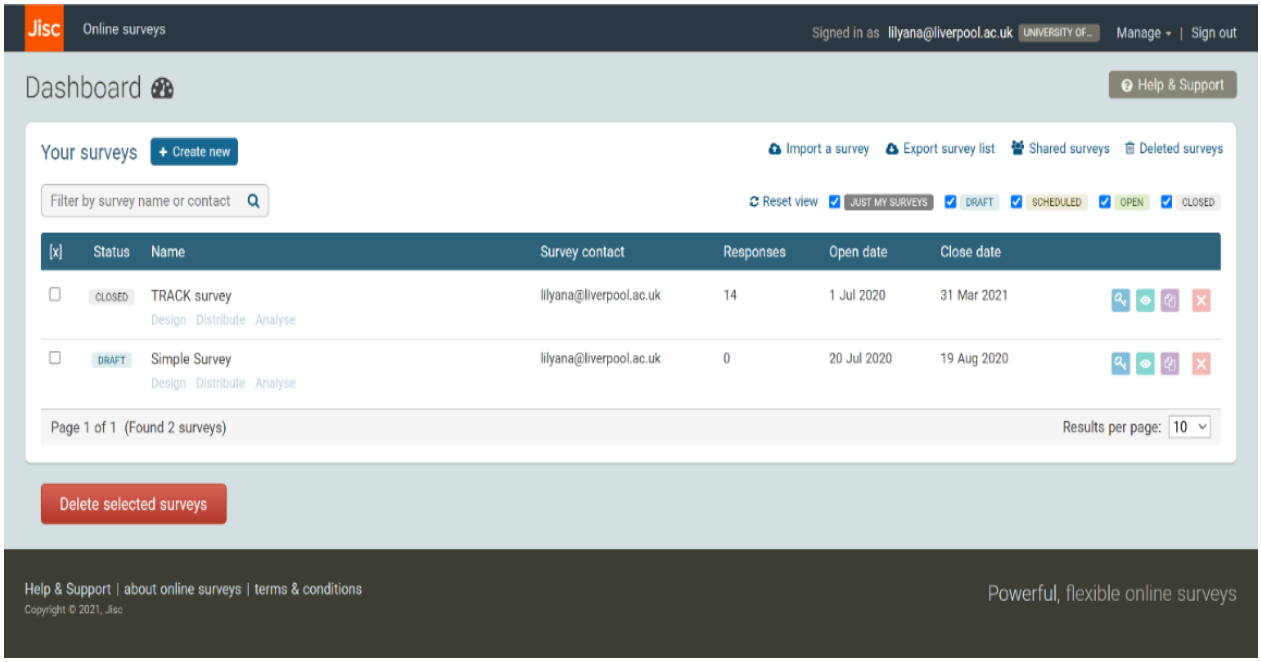


Figure 10. JISC Online Surveys Dashboard

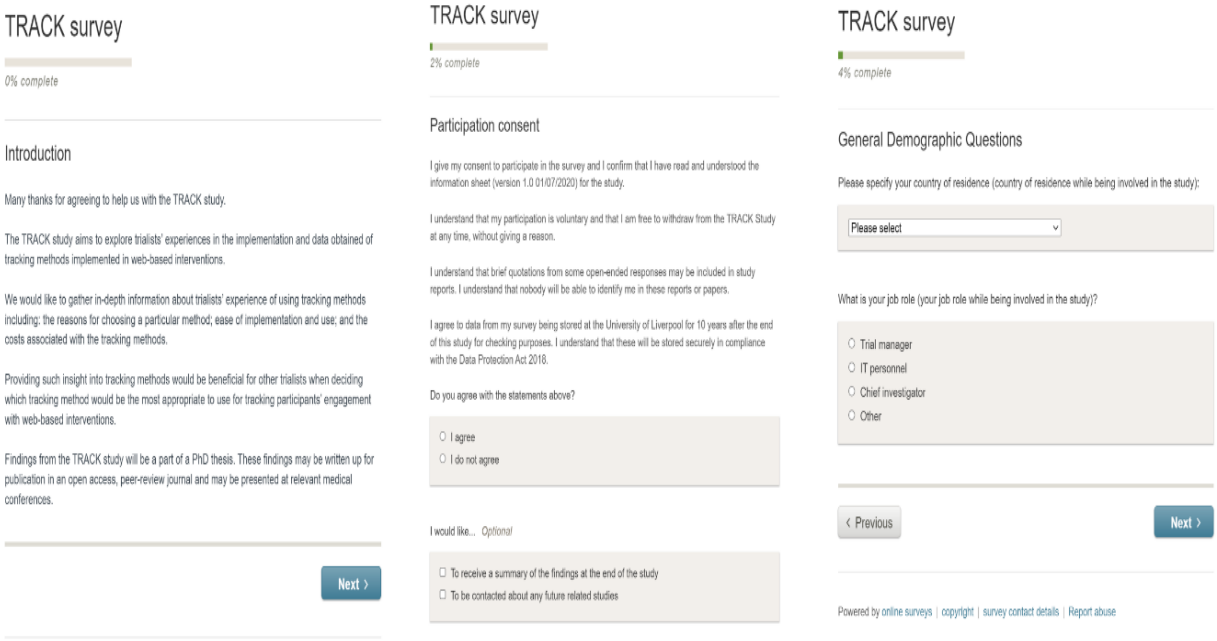


Figure 11. Design of the JISC online survey (first three pages displayed only)

4.6 Sample size

Interviews were conducted until the point of data saturation was reached. This is when the main findings identified in new data are reoccurring from previous interviews and no new information is being discovered that will enhance the findings of the study (103, 104). Based on previously conducted similar studies (105), the anticipated number of interview participants required to reach data saturation was between 15-25.

As the survey was designed as a backup method to capture the views of those who did not respond to an interview invitation or did not have time to complete an interview, a target sample size was not applicable.

4.7 Data analysis

Interviews were video or audio recorded, transcribed verbatim, checked and anonymised. NVivo Pro 12 software (106) was used for organising and indexing data. Data were analysed using a descriptive and thematic approach, which is a research process of examining and identifying themes in data (107). The thematic analysis was conducted in six phases: 1) gaining familiarity with the data, 2) initially coding the data, 3) developing the coding framework, 4) defining and naming themes, 5) completion of coding of transcripts, and 6) producing the results. Data were coded independently and the first transcript was coded with assistance of the supervisors. All further queries on coding were directed to supervisors in cases of uncertainty. The focus was modified to fit with the criterion of catalytic validity (107, 108), whereby findings should be relevant to future research and practice (for example, future use of tracking methods in trials).

Qualitative analysis was used to analyse free text responses to open ended questions in line with the interview data analysis as described above. Quantitative data from questionnaires were extracted from the JISC software in Excel spreadsheets and descriptive tables were created.

Data from the interviews and survey were synthesised and analysed together as the questions in the surveys mirrored those in the interview. Quantitative and qualitative data are presented here together under the same theme. Table 17 shows the approach to qualitative data analyses.

Table 17. Approach to qualitative data analyses

Phase	Description
Gaining familiarity with the data	Transcripts were read and re-read to understand data and get initial ideas.
Initially coding the data	Initial coding framework was developed based on the interview topic guide.
Developing the coding framework	The coding framework was further developed as transcripts were analysed and new themes identified.
Defining and naming themes	The themes (nodes) were defined and reviewed with supervisors during regular meetings.
Completion of coding of transcripts	Transcripts were coded and throughout the process uncertainties were resolved with supervisors. The study aims and potential data saturation were discussed when looking at the data. When data saturation was reached the study was completed. When the coding was completed the next step was the write up for the thesis.
Producing the results	The results and the summary of the results were written ensuring that key findings were identified in accordance with the study aims and relevance to researchers for future trials.

4.8 Confidentiality, data storage and consent withdrawal

Names, email addresses and (optionally) phone numbers were collected from participants who wished to take part in an interview or the survey. These details were used to contact them to arrange interviews, send links to the survey and send electronic copies of the consent form and study findings (if participants requested a copy). The contact details collected were not used for any other purpose.

Audio/video recordings of interviews (not consent discussions) were uploaded securely to a professional transcription company website in accordance with the Data Protection Act 2018.

Some of the interviews were transcribed by a professional company named UK Transcription and the rest were transcribed by the author. The transcripts of the interview audio or video recordings were anonymised as soon as they were received from the transcription company or during the manual transcription process. Any names or potentially identifying information from the surveys and the interviews were removed. Audio and video recordings were deleted once the transcripts had been checked for accuracy.

All data from the interviews and surveys were securely stored in an encrypted electronic file held on a password-protected university drive and archived securely (to be stored for a duration of ten years). Publication of direct quotations from participants is necessary when reporting the results of mixed methods research, but no identifying information appeared in transcripts and therefore no such information appeared in quotations.

Consent forms were stored securely on a university drive separately so that no link between the transcripts and the surveys with the participants could be made. Consent forms were kept for checking purposes only again for a duration of ten years.

Participation was entirely voluntary and participants were able to withdraw at any time without giving a reason. Participants could choose to withdraw consent from all analysis (i.e. all data collected to be deleted) or to withdraw consent from further participation (but allow their data collected to date to be included in analysis). This was explained in the PIS. None of the participants withdrew from the study.

4.9 Risks and benefits

There was no foreseeable risk to participants and no undesired events occurred.

Eligible participants were able to select the time and date of the interview conducted over the telephone or web-based platform (Microsoft TEAMS or Zoom). The online survey could also be conducted at a time convenient for the participants. All interviews were semi-structured yet conducted in a flexible manner to encourage narrative production and enable the interviewer to change topic if needed. Participants were informed that they could terminate the interview, should they wish.

There was no expectation that study participants would benefit directly, although having the chance to express their opinion may have been useful, allowing them to air their views and to reflect on things. Taking part in this study gave study participants the chance to share their

experiences and had their views potentially disseminated as part of the study findings, eventually to reach other trialists who may want to conduct an RCT of web-based interventions and are interested in tracking web usage.

4.10 Study results

The TRACK study included 14 interviews with 16 trialists. The majority of interviews were conducted one to one, with individual trialists. Two interviews involved two trialists from the same trial to assist reflections and discussion. The total number of online surveys completed was 12. At this stage it was felt that data saturation was reached, and study recruitment closed. The recruitment process started in August 2020 and the study ended in March 2021. Although there was an option to have a telephone interview, based on trialists' preferences the interviews were all conducted via Microsoft TEAMS or Zoom only. Results presented here include data from interviews and online surveys.

4.10.1 Demographic data

Data were collected on gender, country of residence while being involved in the study, job role while being involved in the study, and educational background. Fifteen females and 11 males participated, plus two trialists who did not provide gender information on the online survey (Table 18). The study included international trialists from eleven countries, most commonly Australia and USA (Figure 12). In the online survey participants were from Australia (3, 10.7%), USA (3, 10.7%), Germany (2, 7.1%), Belgium (1, 3.6%), Denmark (1, 3.6%), Finland (1, 3.6%), and Switzerland (1, 3.6%). In the interview participants were from Australia (3, 10.7%), USA (3, 10.7%), Canada (3, 10.7%), Netherlands (2, 7.1%), UK (2, 7.1%), Germany (1, 3.6%), Sweden (1, 3.6%), and Switzerland (1, 3.6%).

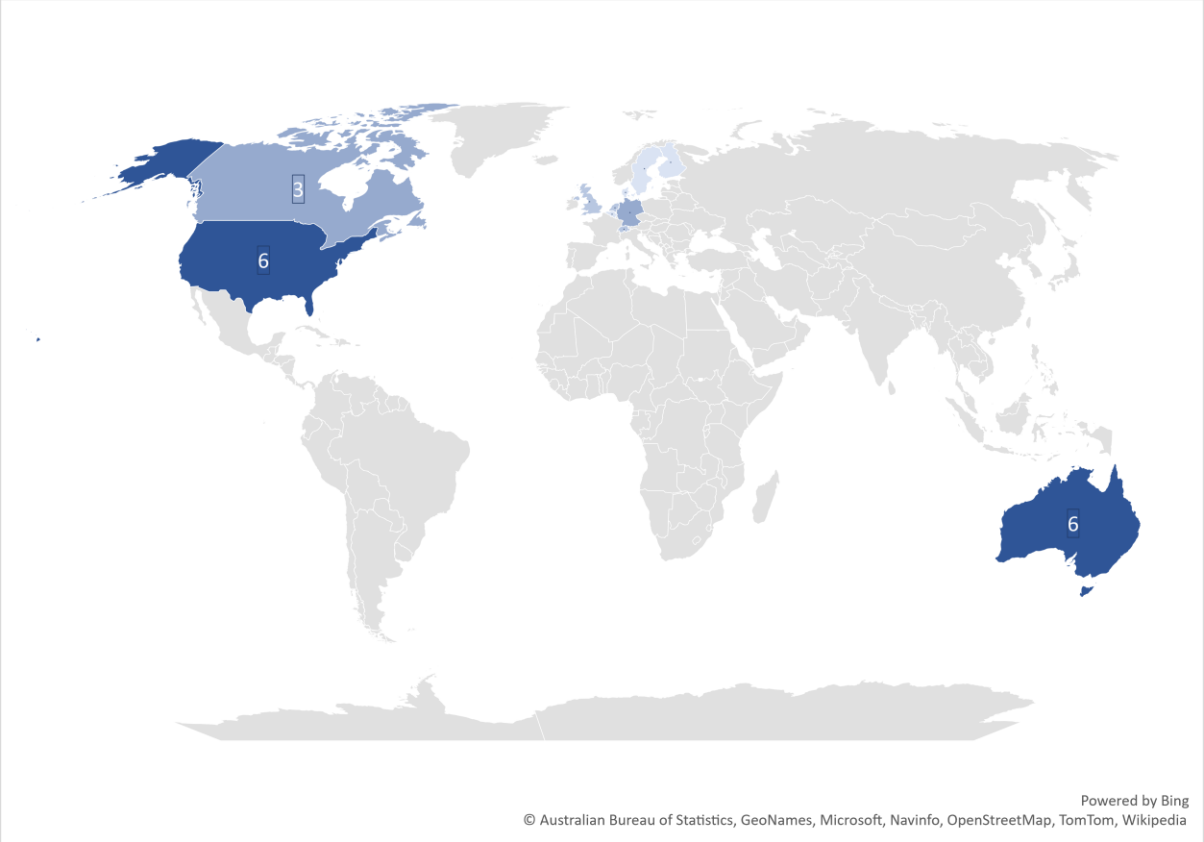


Figure 12. Trialists' country of residence while being involved in the study

Thirteen (46.4%) were researchers, 10 (35.7%) were trial CI and five (17.8%) were part of a trial team (trial manager, project manager, research coordinator, and a study coordinator).

Table 18. Demographic table

Country of residence	**Number (percentage[a])**
Australia	6 (21.4%)
USA	6 (21.4%)
Canada	3 (10.7%)
Germany	3 (10.7%)
United Kingdom	2 (7.1%)
Netherlands	2 (7.1%)
Switzerland	2 (7.1%)
Belgium	1 (3.6%)
Finland	1 (3.6%)
Sweden	1 (3.6%)
Denmark	1 (3.6%)
Gender	
Male	11 (39.3%)
Female	15 (53.6%)

Unknown	2 (7.1%)
Job title	
Researchers	13 (46.4%)
Clinical investigators	10 (35.7%)
Part of a trial team	5 (17.8%)
Area of research	
Psychology	9(32.1%)
Health research	6 (21.4%)
Health Informatics	4 (14.3%)
Medicine	2 (7.1%)
Psychiatry	2 (7.1%)
Physical education	2 (7.1%)
Unknown	2 (7.1%)
Nutrition science	1 (3.6%)

The topic guide did not originally include area of research of participants, but as the interviews progressed, it become apparent that this was important information, in order to understand the challenges faced when implementing and using the tracking methods. Participants working in research with an interest in technology might find it easier to implement tracking methods and their experience might differ from trialists with a non-technical area of research. This was demonstrated by one participant working in health informatics who took a proactive approach to test the accuracy of the tracking method before the trial started.

Information was missing from six early interviews and all surveys with regards to area of research (information was found online). The most common areas of research were psychology (one third) and health research (one fifth).

4.10.2 Tracking methods used

The most commonly used tracking method was GA (44). GA versions were not confirmed with participants but Table 19 lists the potential versions that could have been used based on the date of conducting the trials. GA was featured in seven interviews/surveys, followed by a website platform feature which was included six times (referred as website tracking data in the Chapter 3).

Table 19. Potential GA versions used by trialists

	Tracking method answered	**Tracking method stated in paper or protocol**	**Date that the recruitment into the study started**	**Potential versions used**
Questionnaires				
2	Google Analytics/Universal Analytics	Not stated	2016-2017	Universal Analytics/ Google Tag Manager
3	Google Analytics/Universal Analytics	Google Analytics	November 2012- June 2014	Universal Analytics/ Google Tag Manager
6	Google Analytics/Universal Analytics	Google Analytics	October 2014	Universal Analytics/ Google Tag Manager
8	Google Analytics/Universal Analytics	Google Analytics	August- December 2016	Universal Analytics/ Google Tag Manager
Interviews				
2	Google Analytics	Google Analytics	March 2012- June 2013	Google Analytics/Universal Analytics
4	Google Analytics (used only in the pilot)	Not stated	September 2013- October 2015	Universal Analytics/ Google Tag Manager
5	Google Analytics	Google Analytics	2011-2012	Google Analytics

The website platform feature was embedded on the website, built on the platform and trialists often did not know the name of the platform. For trialists this was usually "programmed within the intervention" and one described it as:

"*Sort of a back office on the website where you can just as provider only you could login to see the statistics of the website usag*e".

P13, Interview

Therefore, trialists who reported using a website platform feature may have used a mainstream method of which they were unaware.

Although there was a number of trialists who knew exactly what tracking method they used and they were familiar with it, six considered the tracking method as a part of the platform on which it was hosted.

"*I suppose it's quite difficult to talk about the tracking and I don't know if you find that, if you're finding this with other researchers, but because it was about the platform, the tracking it's kind of I didn't really think about the tracking as a primary thing when I was doing the study. So, it's kind of hard to think about it as a separate entity, if that makes sense. So, thinking about kind of recommending and for me, it's kind of, I'm thinking about the platform and the tracking is a part of the platform that makes it*".

P16, Interview

Many chose to use server logs, or a bespoke system, as tracking methods and the rest of the methods were scarcely used. Table 20 lists the tracking methods used.

Table 20. Tracking methods used

Tracking method used	Number (percentage[b])
Google Analytics[c] (GA)	7 (25.0%)
Website platform feature	6 (21.4%)
Bespoke software	5 (17.8%)
Server logs	5 (17.8%)
Application logs	1 (3.6%)
Community surveys Joomla! Plugin	1 (3.6%)
Life Guide Software	1 (3.6%)
WassUp WordPress plugin	1 (3.6%)
WURL (Wireless Universal Resource File)	1 (3.6%)

[b] Percentage calculated out of 28 as 26 trials in total but 2 reported using two methods
[c] For one trial it was used only for the pilot phase

Two trialists reported using a second tracking method: in one trial, both GA and server logs were used; in another trial GA was used in the pilot phase and then WassUp WordPress plugin (109) was used for the main trial.

Various comments throughout the interview meetings were raised by trialists with regards to finding an appropriate tracking method for study purposes. The trialist that used the Life Guide software mentioned satisfaction with this method and concern if the method would no longer be available in the future. The reason is that this method is free to use, which makes it very attractive to researchers especially those with a limited research budget. Two trialists who were using bespoke software noted that they would benefit from learning about existing tracking methods, especially the ones that are free. One trialist who used website platform feature software was unaware of different tracking methods, and others that used GA and application logs were also interested to learn more about available methods.

"Alternative methods to tracking that are easy to use."

P7, Questionnaire

4.10.3 Tracking methods preferences

The most frequent reason cited for using a particular tracking method was previous experience, as answered by more than one third of participants (9, 34.6%). Others common reasons included the method being free to use (7, 26.9%), recommended (6, 23.1%), and

already in place (5, 19.2%). Other reasons included data storage capabilities of the method, ease of use, level of usage detail recorded by the method, well established software, and suitability for the intervention format. Some trialists stated more than one reason for choosing the tracking method.

"*Um, it's free to use and open source. So, it means that anybody could download it and use it without having to pay for it. That was a big driver and the driver is the amount of control that it gave you as a researcher, so you could specify exactly what you wanted to monitor, what you wanted to record, you could log in at any point to check participants as progress or their flow of the online intervention at any point. It just gives you a lot of control and also, it's free. Yeah, so it completely cut out the need for any software developers*".

P6, Interview

Although experience with the method was one of most common reasons to choose a given method, in more than half of the trials (15, 57.7%) it was reported that trialists did not have experience of using the method previously. The reasons provided for choosing the tracking methods are given in Figure 13. Other reasons include amount of control over usage tracking, no alternative and open source program.

Interestingly, trialists often did not consider using any other tracking method (21, 80.8 %). Those who did consider other methods (5, 19.2%) noted server logs, GA and Life Guide software as alternatives.

Interviews and survey responses also indicated that most trialists (18, 69.2%) did not undertake any research into tracking methods. Five (19.2%) discussed or consulted with co-investigators and developers (internal) or other trialists (external). Two (11.5%) trialists researched alternative tracking methods and made comparison between methods.

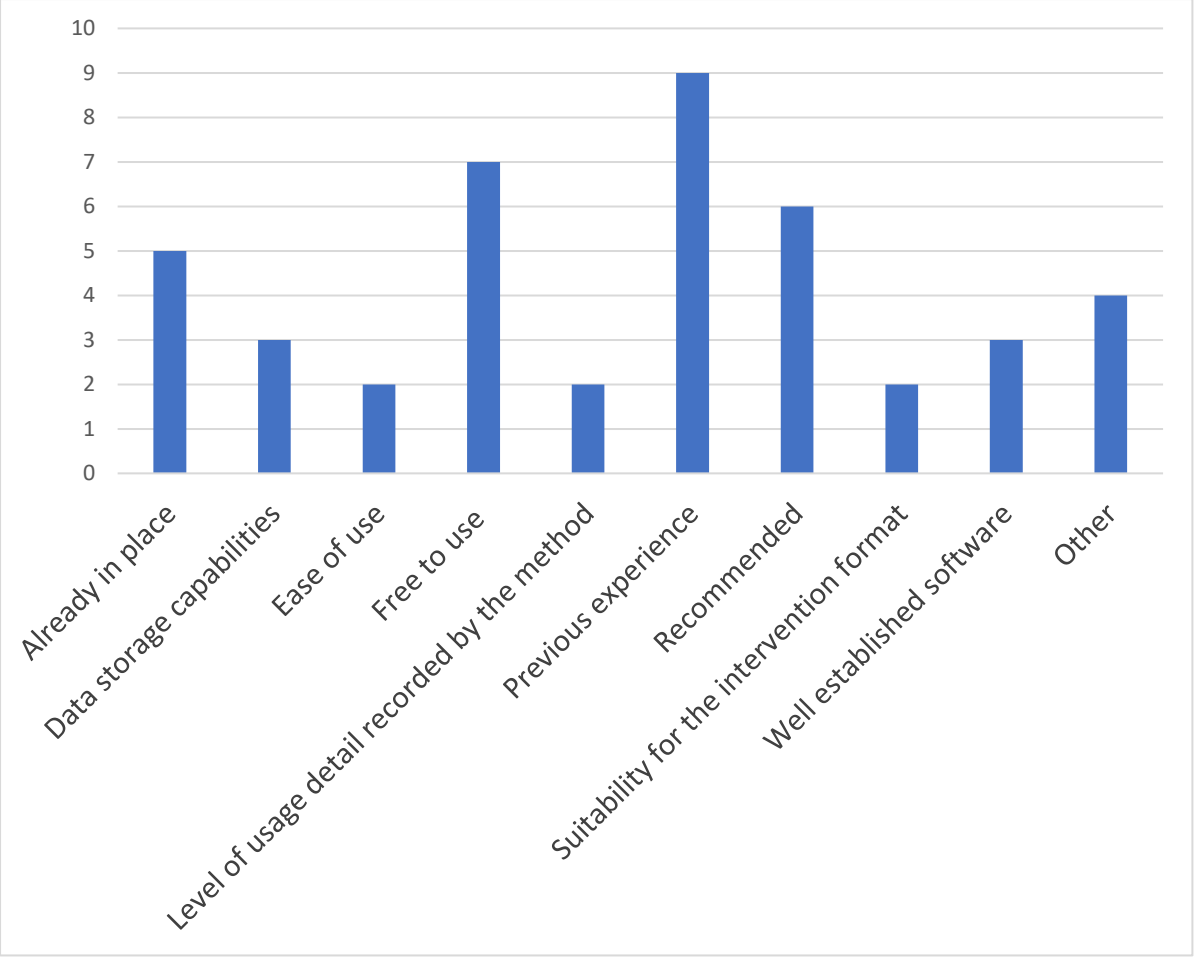


Figure 13. Reasons for choosing the tracking methods

4.10.4 Implementation and testing of the tracking methods

The majority of trialists (24, 92.3%) relied on someone else to implement their tracking method, usually a developer (22, 84.6%). In one trial (3.8%) it was reported that a webmaster implemented the method, and in another (1, 3.8%), a professor in psychology was responsible for implementation. In only two trials (7.8%), trialists had implemented the method by themselves and reported having no challenges in doing so. Those who implemented the method itself had used Life Guide software and Community surveys Joomla! plugin as tracking methods.

The topic guide was developed during the study to ask trialists if they had implemented the tracking method themselves and, if so, whether they had a testing phase to check for accuracy. Both trialists who had implemented the method themselves had included a testing phase to check for accuracy of their data.

Although the topic guide did not include questioning the trialists who did not implement their method about whether a testing phase was used, this topic occasionally arose during the interviews. Six trialists stated there was a testing phase to check for accuracy of usage data. Three confirmed that they not having a testing phase while one was unsure as they assumed that the developer who implemented the method may have done so at an earlier stage. From the online surveys no information was obtained on testing phase as all trialists reported that someone else was responsible for implementing the tracking method.

When describing the testing phase, trialists noted that they had test users that simulated different scenarios; these were later checked to see if they matched with the data received from the tracking methods. They all agreed that they wanted to check before going ahead with the real-world collection of data and ensure that everything was being recorded properly.

"*Yes, we do extensive testing. So, we actually, um, I think we worked with maybe eight or 10 different testers who tested in different like different web browsers, different scenarios. So, we do like thorough testing to check that everything works as it should, and that everything is recorded as it should, yeah".*

P6, Interview

One trialist especially acknowledged the importance of having a testing phase.

"*I would say the most important part is to test it before using it. So, you want to make sure that these analytics are working fine. So, do everything necessary to test these analytics before using them. Because that's normal, in IT you might have an error, a bug what you call it in the system so it might give you a number but maybe is not the correct number because something is missing in the way they collected these analytics*".

P15, Interview

4.10.5 Advantages and disadvantages of the tracking methods

Trialists noted lots of advantages associated with the tracking methods, such as the ability to track across programs, ease of extracting data or not requiring software developer knowledge for implementation or use of the method.

The main advantage of tracking methods, which was noted by eight trialists, was the levels of detail available in the usage information. For example, the ability to measure how much time people actually spent on various parts of the program and to track other usage metrics they needed.

"*What were they looking at? How often did they visit the site? Those were the things that made this particular plugin an advantage*".

P1, Interview 4

Other advantages included: the consistency of tracking; good user interface; the fact that they were able to track patients without influencing them; the method being free or easy to use; the method being already in place; and that the method automatically tracked usage data. Objective metrics were also noted by some trialists, with recognition that usage data enabled them to see how participants interacted with the web-based intervention and the content. Trialists often noted multiple advantages of their tracking methods.

"*Detailed information and pretty straightforward to use*".

P6, Questionnaire

The results of the advantages per tracking method are summarised in Figure 14.

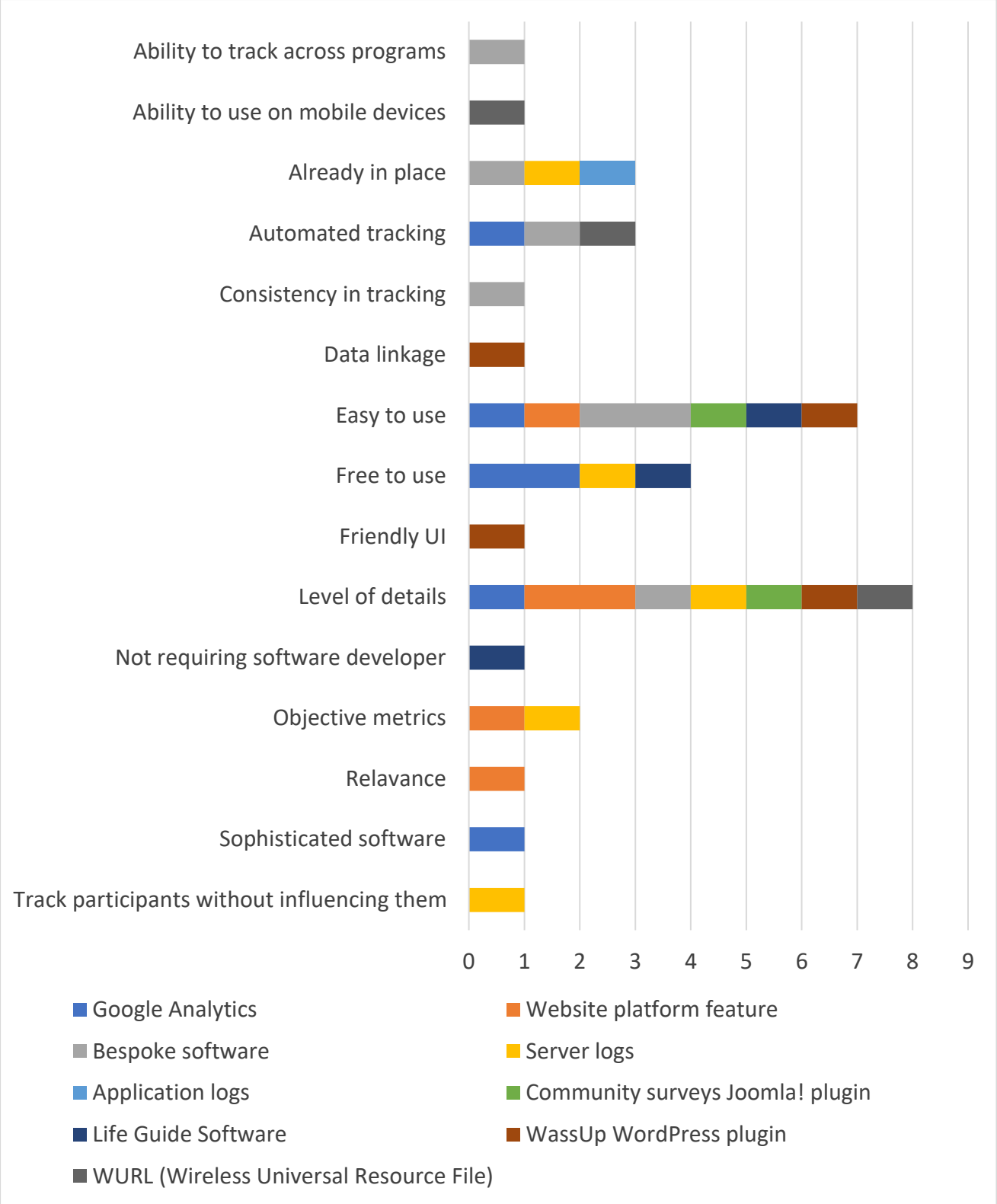


Figure 14. Advantages associated with the tracking methods

The main noted disadvantage of tracking methods was difficulties with the data (reported in 23, 88.5%, trials). Trialists had difficulties understanding the data or the format (e.g. in the case of unstructured data), which made it difficult for them to draw conclusions. They also noted difficulties handling the data, which also included extracting data or data linkage. All three trialists that reported difficulties with handling the data used server logs as a tracking method. Three of the four trialists who reported issues with understanding the data again used server logs as well as two of the three trialists who reported issues with unstructured data. Overall, all trialists who noted using server logs reported disadvantages with the data, often noting more than one.

"*One of the downsides is that the data is very hard to handle, like it's a huge amount of lines with so many logs and it's very hard to make, to receive meaningful measures from that*".

P14, Interview

Trialists also reported difficulties with the analyses of data, meaning that there were unable to tailor the analyses, or they needed to develop analysis algorithms specifically for their project.
Difficulties were associated with the functionality and the design of the UI and the back end of the tracking methods.

"I thought, from a user-friendly perspective, I thought it could have been better organised on the back-end."

P1, Interview 4

Other disadvantages with regards to the limitations in usage tracking, for example not tracking all usage metrics.

"It provided us with nothing more than usage time in minutes (no usage time of specific modules of the intervention)."

P5, Questionnaire

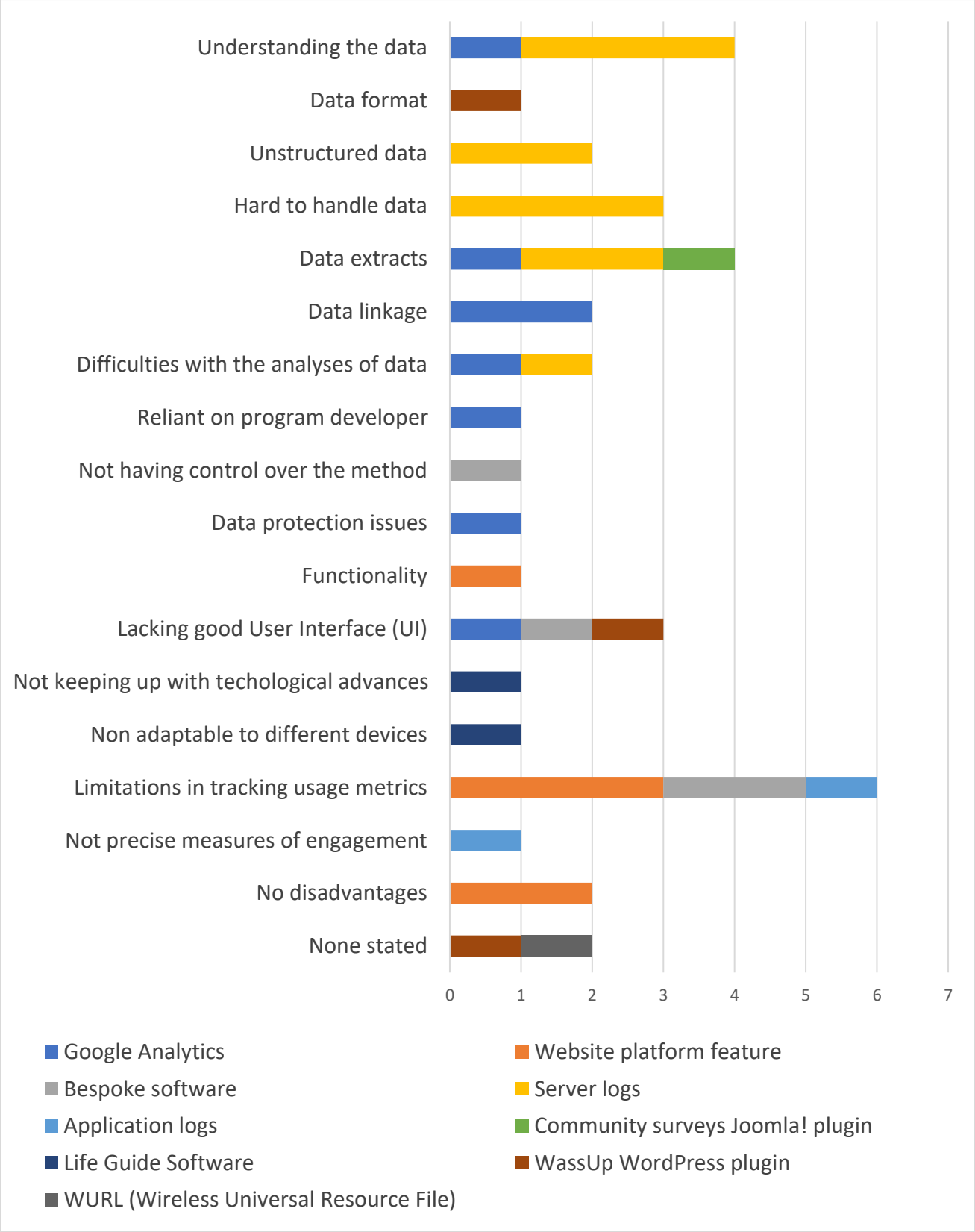


Figure 15. Disadvantages associated with the tracking methods

In two (7.8%) trials, trialists specifically said that their tracking methods did not have any disadvantages ("No disadvantages"). Both trialists used website platform feature as a tracking method. Two trialists (7.8%) did not respond to the question ("None stated"). The summary of the disadvantages of the tracking methods are given in Figure 15.

More than half of trialists (15, 57.7%) used a method with unlimited storage capabilities. Four (15.4%) reported that they could have stored data for a limited period, one for a duration of 5-10 years, one for a duration of 2-5 years, and two for a duration of less than six months. Although the question related to duration of time that data could have been stored, some trialists also gave input into storage capabilities in terms of number of users in the system. Their most common answer was that they could have had hundreds or thousands of users.

The most widely used tool to analyse data was SPSS, followed by R as shown on Table 21.

Table 21. Tools to analyse the data

Tools to analyse the data	**Number (percentage)**
SPSS	16 (61.5%)
R	6 (23.1%)
SAS	3 (11.5%)
Stata	3 (11.5%)
Excel	2 (7.7%)
Bespoke code	2 (7.7%)
FileMaker Pro	1 (3.8%)
Life Guide Visualisation Tool	1 (3.8%)
MATLAB	1 (3.8%)
Mplus	1 (3.8%)
Python	1 (3.8%)
SQL	1 (3.8%)

Results regarding use of the same tracking method again if appropriate are given in Figure 16. The majority of trialists (23, 82.1%) reported that they would use the same tracking method again, if appropriate. Some reported that would definitely use the method again, while others would use it depending on cost, data imputation, analysis of results, more detailed tracking or alongside other tracking method for more detailed tracking. Six trialists were very satisfied and reported that they are still using it and will continue to use it. Three (10.7%) felt that they would not use the method again and three (10.7%) said that their decision will depend on further research.

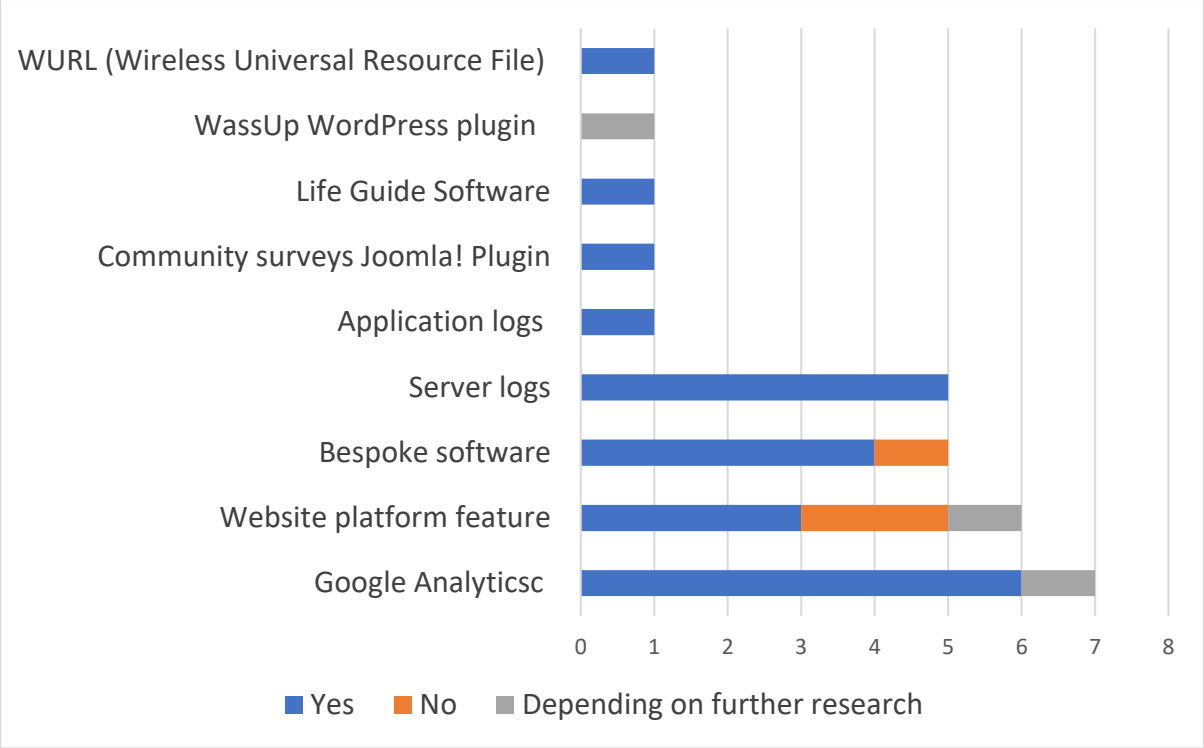


Figure 16. Use of a same tracking method if appropriate

The majority of trialists (18, 69.2%) would recommend the tracking method they used to other trialists. One would recommend the method but would inform other researchers of its cost as the method used at the time of their trial was free, but that is not the case anymore. Another trialist would recommend the method together with the platform. Four (15.4%) would not recommend the method, three (11.5%) said it would depend on the study and one (3.8%) was unsure. Results are presented in Figure 17.

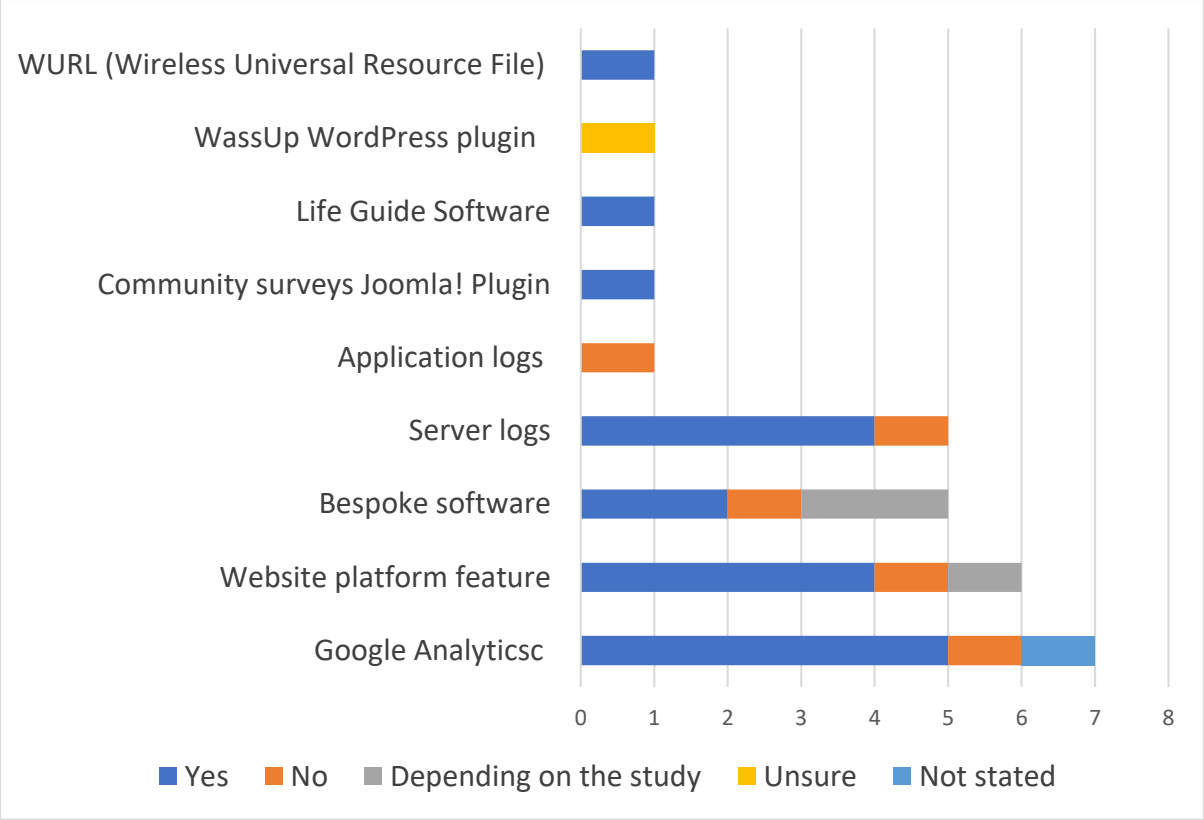


Figure 17. Would interviewees recommend the tracking method?

4.10.6 Usage metrics

Time spent on site was the most frequently used usage metric, followed by logins. If the web-based intervention consisted of interactive components such as modules, assignments and sessions, the trialists were interested in tracking access and completion of these components.

"*So, part of it was we tracked participants accessing the so-called modules which would be parts of the intervention of the cognitive behavioural intervention. As well as we tracked their completion of assignments in those modules*".

P9, Interview

Depending on the content of the web-based interventions, trialists could have also tracked forum activities, opened messages, number of posts made, number of worksheets completed etc (noted as "Others" in Table 22). Trialists were also interested in tracking video usage (number of videos viewed, length of videos viewed etc.).

"*So, what we tracked is the use of this website. So how, when people logged in, how many, so how many times they logged in and how many minutes they've spent specifically on the videos because the website contained videos for mindfulness right. And we wanted to track how many seconds so, it was for students so the students watched the videos. So, every video. So, we tracked the use of these videos, how many seconds they played these videos and watched them*".

P15, Interview

Table 22. Usage metrics recorded

Usage metrics	**Number (percentage[d])**
Time spent on site	20 (71.4%)
Logins	17 (60.7%)
Modules	16 (57.1%)
Device used	6 (21.4%)
Sessions	5 (17.9%)
Video usage	5 (17.9%)
Timestamps	4 (14.3 %)
Assignments	3 (10.7%)
Browser type	3 (10.7%)
Lessons	3 (10.7%)
Visits	3 (10.7%)
Clicks	1 (3.6%)
External links	1 (3.6%)
Documents downloads	1 (3.6%)
Others	19 (67.7%)

[d] Percentage calculated out of 28 reported tracking methods

Figure 18 shows usage metrics that trialists noted to be tracked by the tracking method(s) used in their trial.

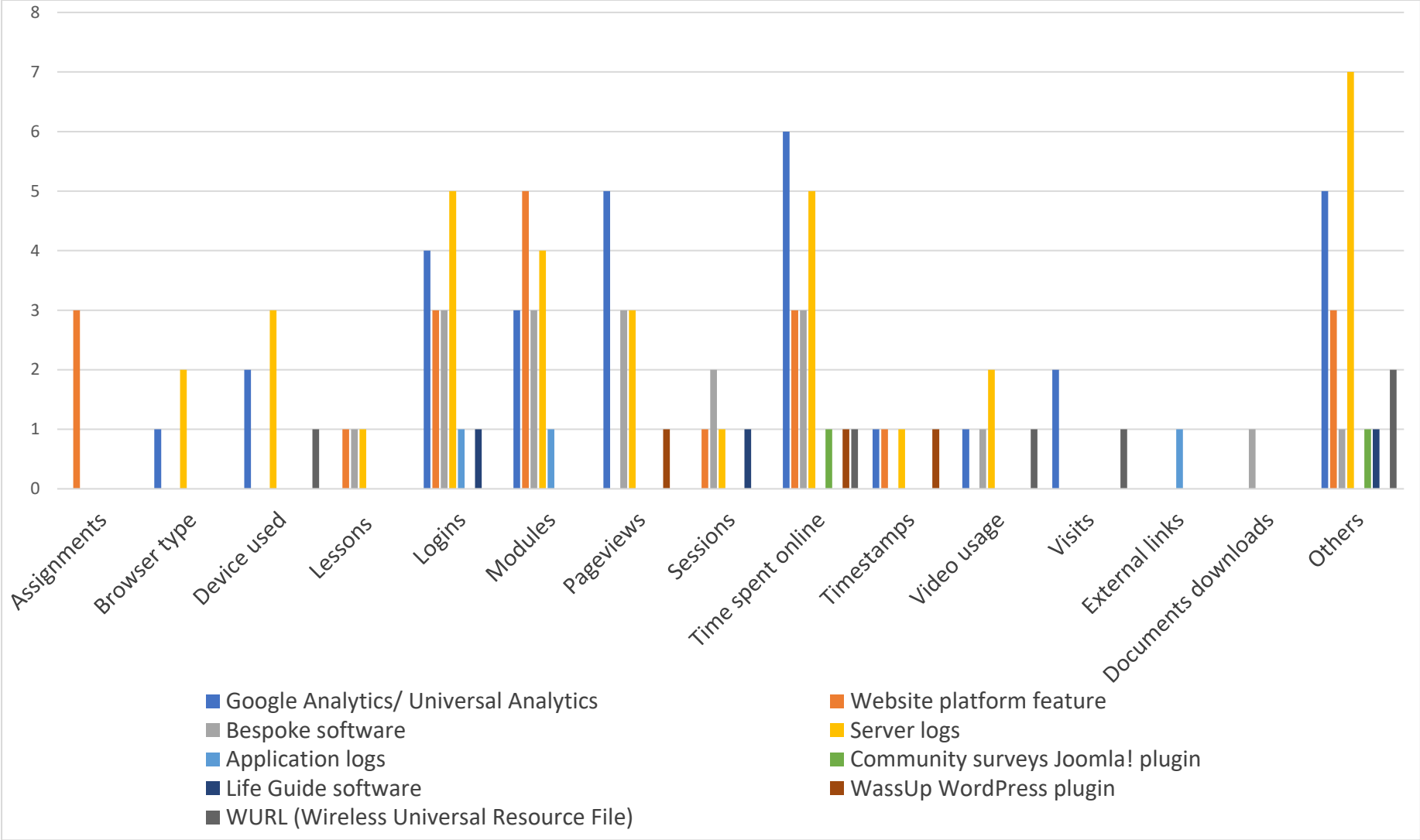


Figure 18. Usage metrics recorded per tracking method

The inability to track all usage metrics of interest was also noted by some trialists. The list of desired usage metrics per tracking method is given in Figure 19. However, the mention of certain usage metrics that they would have liked did not necessarily mean that the tracking method could not track those, as sometimes it can be a matter of cost, additional time for setting up, slowing down the performance of the web-based intervention website or not being aware that a metric could in fact be tracked by the tracking method. Some usage metrics are tracked by default while others are not; in order to track those metrics not included in the default settings, additional development during the setup phase may be needed, such as adding extra code. In Chapter 5 examples of enabling certain usage metrics that trackers do not track in their default settings are given, but since there are numerous tracking methods their configuration depends on the method itself and the metrics needed.

"Let's see. And maybe how they navigate through the website, like do they click first and second, and if you can- Are there some patterns in it or not? For most click patterns. But then they said that the website would be very slow, when they install this kind of software, so that was not an option."

P3, Interview

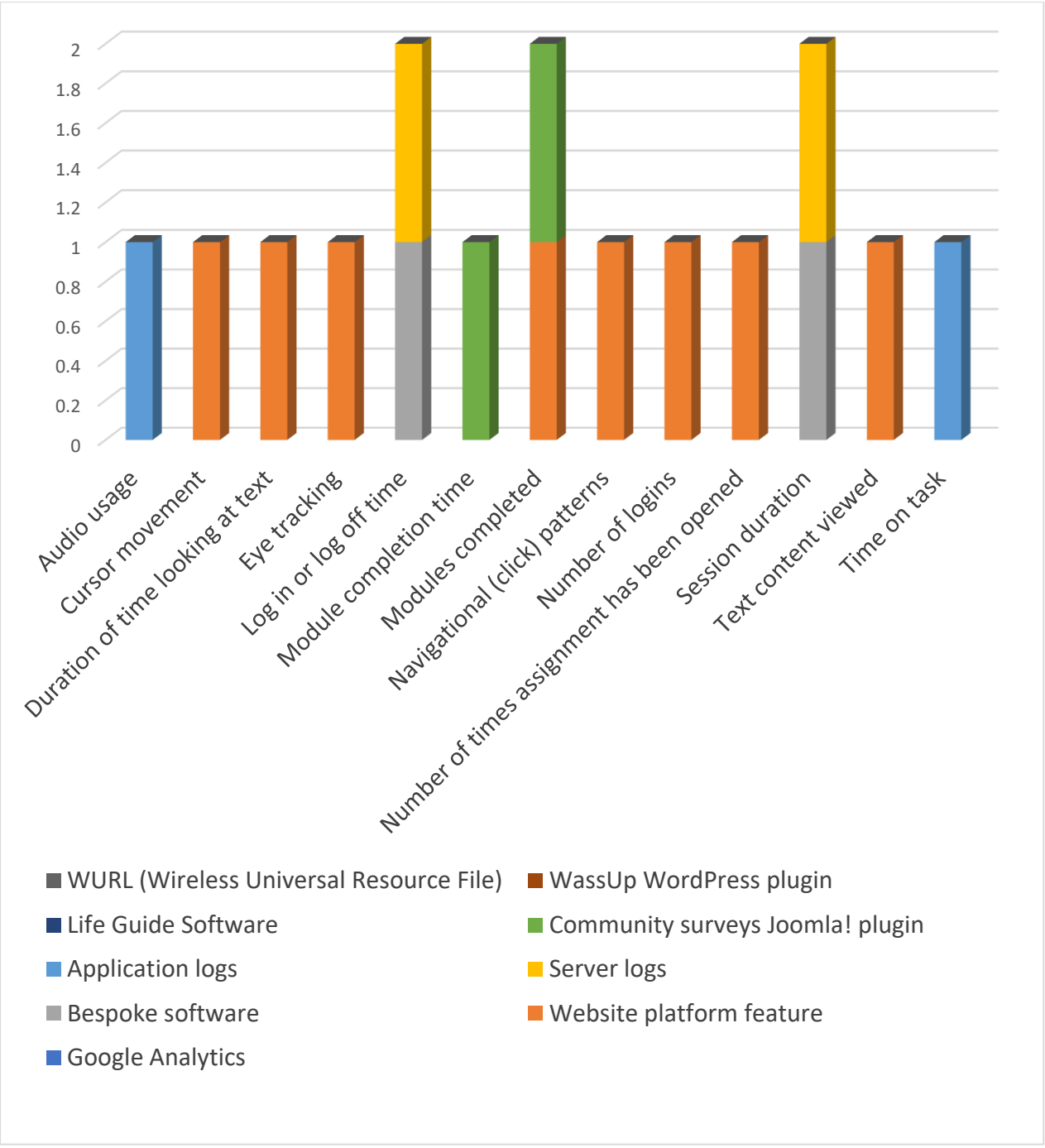


Figure 19. Desired usage metrics

4.10.7 Costs associated with the tracking methods

Nineteen trialists (73.1%) did not pay for the tracking method. Of the seven trialists (26.9%) who paid for the tracking method, five paid for the method as part of the platform so the cost was calculated as a whole package.

Trialists who noted paying for the methods itself used Community surveys Joomla! plugin (1/7, 14.3%) and website platform feature (1/7, 14.3%). The trialists who paid for the method as part of a platform used bespoke software (4/5, 80%) and website platform feature (1/5, 20%).

Some trialists did not know the cost of their tracking methods. Others reported costs that varied widely according to the tracking method used. One noted paying around £1000 for the tracking method together with the platform while another that had a bespoke system developed for them, used for a duration of over a decade, reported paying significantly more (over £200,000 but this covered the development of the platform on which they run a number of interventions). For this trialist cost was a major issue.

"*Cost is a major issue. And I guess that's one of the probably not helpful for your interview, but I think that's one of the things that at least historically people have underestimated in online interventions, the cost of maintaining a secure platform or intervention and keeping it up to date and everything*".

P10, Interview

Only one trialist was able to quote the cost of the tracking method itself, the Community surveys Joomla! plugin £55 ($75); they also stated that there were additional associated costs totalling around £350.

Trialists noted a variety of additional costs associated with their tracking methods. These included costs for a backup mechanism, data analysis, data extraction, hosting on the server, implementation, keeping up to date, licences for extensions, mailing component, maintenance, receiving tracking data, software firewalls, technical support, testing and checking, and to use software during research (Figure 20).

"We did actually, we cost it a very small amount for Life Guide technical support and I think they charged us something like hundred pounds to hosted on their server. So, like £100 total and I can't remember what we cost it for Life Guide support, but it would have been something like a really small percentage of a researchers' time. So, maybe an hour a week".

P6, Interview

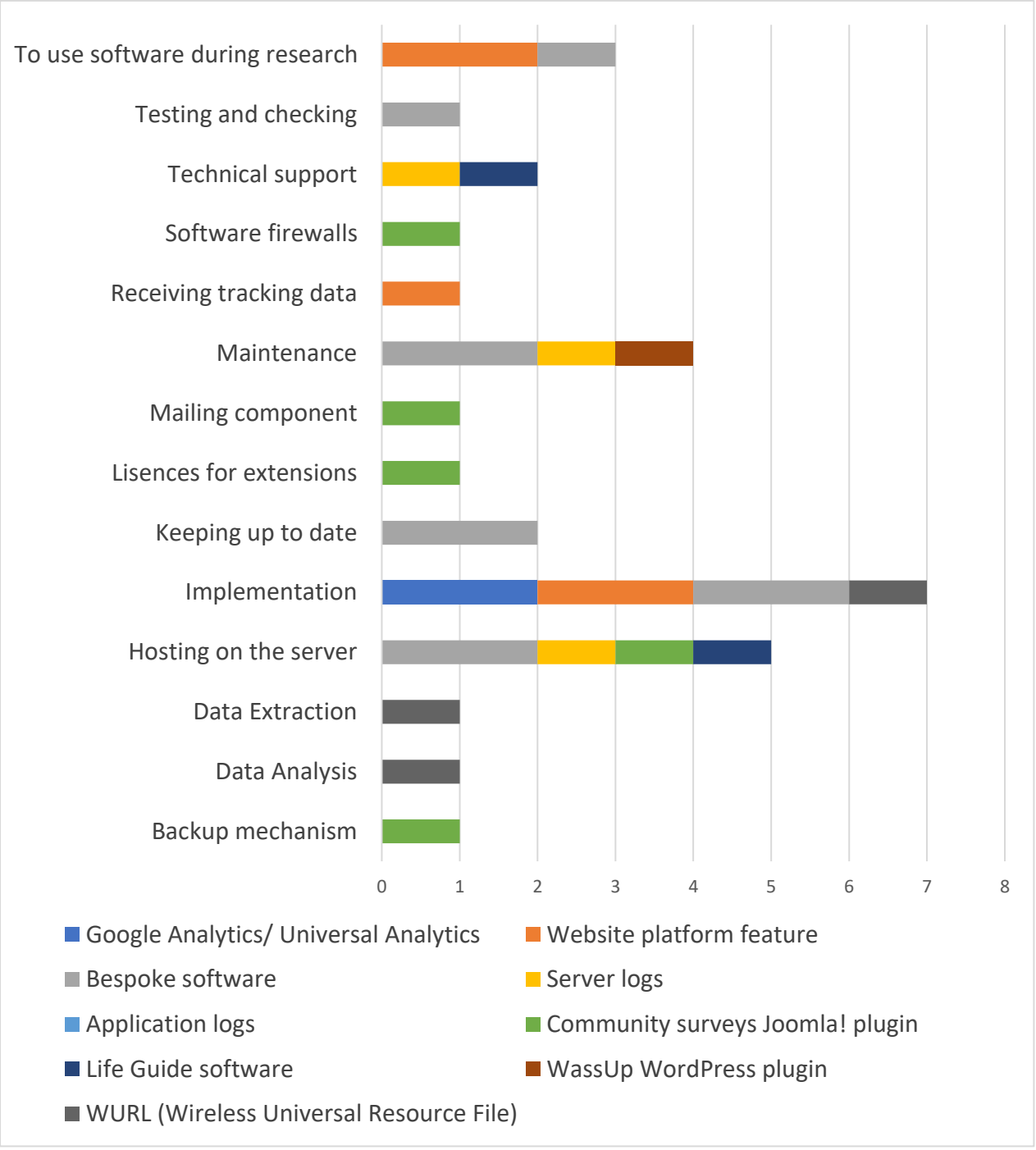


Figure 20. Additional costs associated with the tracking methods

The seven trialists who paid for the tracking method were generally in favour of paying. One stated that they expected the tracking data received to be more structured, although if there is a free method available that presumably provided more structured data that would have been a better option. Two answered that they would definitely pay for a tracking method while four said they would pay depending on cost and value it would bring to the web-based intervention.

"*Yeah, there's, it's unavoidable, you have to pay for that. I mean, everything you need to implement in IT, you have to pay for it. So, there is no way around it. So, if you need it yes, of course*".

P15, Interview

Four trialists of those who paid for the tracking method (4/7, 57.1%) said that the cost of the method did not influence their decision to use the method.

Trialists who used free tracking methods were also asked whether they think that using a free tracking method was the best option or if investment in a tracking method would have brought better results. Nine of those (9/19, 47.4%) were in favour of using a free tracking method and one trialist said that they are in favour of using the method but only if it remains to be free. Four trialists (4/19, 21%) said that they were in favour of an investment in a tracking method. Three trialists (3/19, 15.8%) were unsure and three did not state their answer (3/19, 15.8%). One trialist (1/19, 5.3%) answered that their decision will depend on the quality of investment.

"*Yeah, I think it's depends on the quality of what that investment would yield. So, if it saves time of the study team having to figure it out things and ran those small pieces of code to get the answers they wanted and if they felt more comfortable with the dashboard that may be was easily accessible, understandable and customisable it probably it would be worth an investment of several thousand dollars or so. Um, if that isn't the case if does the same things then use free*".

P2, Interview 4

4.10.8 Additional comments

At the very end of the interview or the online survey, the participants were given a chance to add any additional comments they might have, anything they wished to add about their experience with the tracking method. Additional comments were also gathered during the interviews/surveys when trialists moved from the current subject and talked about other things regarding trials of web-based interventions and the tracking methods used.

4.10.8.1 Technology and behaviour change

Some trialists talked about the blend of technology and behaviour change. They talked about the connection between technology and behaviour and the importance of utilising the technology in the right manner but also to understand how people use technology currently.

4.10.8.2 Calculating exact time on intervention

When talking about calculating exact time on the web-based intervention, many wanted to know exactly how much time participants spent on the intervention and to calculate the exact time spent on doing certain activities, for example how long it took someone to answer a specific question.

4.10.8.3 Challenge to figure it out usage data

Challenges working out what to do with the usage data, what useful information can be taken from usage data and what is clinically relevant were also noted. The trialists also talked about difficulties interpreting the data, in particular making conclusions when some people engage more than others, given the fact that some participants need more time to process information.

4.10.8.4 Comments associated with engagement

Trialists also made various comments related to the term “engagement”. Some talked about the fact that engagement can be subjective as patients can engage differently and the trajectory can differ.

4.10.8.5 Value of experience

Lastly trialists talked about the valuable experience gained from their trials. This related to the research into collection and analysis of their data to inform future usage, the experience with the use of their tracking methods and designing a web-based intervention.
Illustrative quotations for these themes are shown in the table of additional comments Table 23.

Table 23. Supportive table of additional comments

Description	Additional comments
Technology and behaviour change	"*I think you really ought to – people ought to – understand it more deeply and broadly than just, "Let's just go make a program," and throw it into an RCT, and publish, and, "Oh, boy, we're off on our journey." I think there's so much more to it that's a blend of technology and behaviour change*". P1, Interview
Calculating exact time on intervention	*"How and when to exclude track entries for time spent when it becomes obvious that someone is just online and does not work on the intervention."* P3, Questionnaire
Challenge to figure it out usage data	"*I mentioned already the complication of almost being able to track too much and trying to figure out: what's useful information about all data? How do you shrink down all the data into useful information, and then what do you make of that utility*"? P1, Interview
Comments associated with engagement	"*Maybe there's some patient that done, just one part of the intervention one session, but it was so engaging for them in their behaviour and have more benefits than one patient that saw everything but the engagement was not there, because there's the engagement in terms of the*

	behaviour, you know, objectively, to look like anything but the engagement". P1, Interview 7
Value of experience	"*Um, yeah, I think it's very valuable extra information as I told you I have now finished two other randomised trials where we have used a lot of tracking devices including GPS and everything. We are actually particularly looking at the usage of those things and how we can perhaps improve this in the future. So, it gives a lot of information, of course, on how we can make or how can we meet the needs of the users for the better.*" P13, Interview

4.11 Strengths and limitations of the TRACK study

To the best of the author's knowledge, evaluating trialists' experience of using tracking methods for web-based interventions has not been done previously. This is the first study exploring in depth trialists' experience of the use of tracking methods for the purpose of these interventions. The most popular tracking methods used currently, such as GA and server logs, were investigated.

The TRACK study included trialists from multiple countries. Participation invites were sent to all newly published trials identified by the search. Due to the COVID-10 pandemic, interviews could only be made remote without any personal face-to-face contact which might have been more comfortable for the participants. However, this enabled the author to maximise the number of participants and to easily arrange a convenient date and time for the participants. As in the SR, the TRACK study excluded trials which utilised mobile phone applications or social media interventions as the aim of the thesis was to focus on web usage data.

4.12 Discussion

When deciding on a tracking method to use, trialists often chose well known methods, most commonly GA which is currently the most popular method and used widely in health research (3, 110-112). Following its launch in 2005 (113), GA has been updated several times. The subsequent version was Universal Analytics in 2012 that introduced the Google Tag Manager (114). This version included several improvements such as enabling to track users across different devices by the use of the User ID (115). Trialists who took part in the interviews and surveys were not specifically asked to state the GA version used but based on the date of conducting the trial it was possible to gauge what version they were likely to have been using. Several misconceptions appeared with regards to GA related to video usage, which particular components could be tracked, and uniquely identifying users. The reason for this misconception is that GA in its basic core version provides more aggregated data and various versions provide different options. There are certain ways to overcome these issues but because in the basic version these are not set by default, it is easy to presume that GA cannot track individual's usage metrics or video usage. To overcome this the trialists can switch to GA's newer versions such as Universal Analytics or Google Tag Manager (116). However, the

execution is not straightforward and requires some technical knowledge and coding, skills which the trialists may not have (117). Also depending on when the trial was conducted, features available in later versions may not have been available at the time. So, although this also may be due to the version used it can also be due to the fact that technical knowledge is required to understand what exactly can be done using this method. One of the trialists who used GA understood that it was possible to uniquely identify users, but that he needed a developer's help to do so.

Other commonly used methods were bespoke software and server logs. Some trialists noted that their bespoke system was developed over many years and they use it for a range of different web-based interventions. These trialists opted for a bespoke method because they wanted a method tailored to their web-based interventions and one that was able to track all usage metrics required. Although advantageous, a tailored tracking method does incur costs. Server logs were also a popular choice as they are easily accessible and obtained. These are used often in health research (118-120). This method provides access to essential data that can be stored for an unlimited time (121).

Trialists who reported using a website platform feature may have used a known method of which they were unaware, as discovered in one trial. That trialist reported using a website platform feature on a bespoke platform, whereas they were actually using Google Tag Manager on a WordPress system. As discussed earlier, because not all trialists had extensive technical knowledge about their tracking method, which was often a feature embedded in the platform used for tracking, it is very likely that others also used known systems of which they were unaware.

Only in two trials was more than one tracking method used. In one trial, GA was used alongside server logs to provide more in-depth usage data. In a second trial, the trialists dismissed GA after using it in the pilot phase because it did not provide them with enough individual user level information, so they used the WassUp plugin for the main trial. In this trial they did not have two methods recording the usage data simultaneously so really there was only one trial that used two methods at the same time for comparison. This suggests that majority of trialists rarely opt for a second tracking method to compare usage data or to obtain even more data.

Findings from this study also suggest that trialists did not consider using other tracking methods (21, 80.8%) when choosing a tracking method and that they did not undertake any research about their methods (18, 69.2%).

Trialists noted various reasons for choosing the methods, most commonly previous experience. However, a high number of trialists reported not having previous experience of using the method. Other main reasons included characteristics such as being free to use, already in place or recommended by developers or colleagues.

The most noted reason for using GA was having previous experience with this program. The advantage of already being in place was the most common reason for choosing a website platform feature and being free to use for choosing the server logs. Bespoke software was most frequently chosen due to previous experience or no alternative.

As almost all participants (24, 92.3%) relied on a developer to implement their method, it is clear that trialists often need technical assistance with implementing the tracking method. A couple of trialists (2, 7.7%) implemented the method by themselves, and they reported having no challenges in doing so. Both of these trialists included a testing phase. One trialist in particular acknowledged the importance of having a testing phase as part of their additional comments at the end of the interview. Unfortunately, the topic guide initially did not include a question about whether there was a testing phase, but in eight interviews this issue was discussed and four trialists mentioned having a testing phase for their trials.

A range of advantages were associated with the tracking methods, including the level of usage data provided, ability to track across programs, ability to track participants without influencing them, and being free or easy to use or extract data. These advantages are noted on their official sites and various online blogs (51, 122-124). Disadvantages depended on the method used; some methods could not track certain usage metrics while other gave data which were difficult to handle. The latter was commonly associated with server logs, in which data come in a file of hundreds of lines (125). All trialists who used server logs reported challenges with the data, often noting more than one. Trialists had difficulties with the extraction and handling of data and understanding unstructured data, which made it difficult for them to draw conclusions. Online literature supports this finding and online blogs can be found with guidance on how to analyse server logs (125, 126). Dissemination of the advantages and disadvantages given for each method in this chapter would have the potential to help trialists in future trials.

Trialists can track various usage metrics in order to “paint a picture” about participants’ behaviour and interaction on the intervention again depending on the content of the intervention. Not surprisingly, time spent on site was most often tracked across the majority of tracking methods (20, 71.4%) followed by logins (17, 60.7%) and modules (16, 57.1%). This corresponds with findings in literature which suggest that these metrics are most commonly recorded (127-130). These usage metrics were also commonly reported in the systematic review as well. Other usage metrics noted by trialists included device used, video usage, browser type or other metrics all of which provide important and valuable information to trialists.

Generally, trialists would use their methods again (23, 82.1%) and would recommend them to other trialists (18, 69.2%). Three trialists (10.7%%) would not use their tracking methods again and three (10.7%) answered that their decision will depend on further research and other factors. Of those who would not use the methods again, two were using a website platform feature and the other used bespoke software. These trialists stated that their tracking methods did not meet their expectations and they would prefer a method that provided more usage information.

The number of trialists who used a free tracking method was much higher (19, 73.1%) than those who paid for a tracking method (7, 26.3%). The majority of the trialists that paid for the method paid also paid for the platform; only in a very small number of trials (2, 7.7%) trialists actually paid for the method itself.

Trialists also reported additional costs associated with the method. Additional costs that were reported by trialists who used a free tracking method suggests that there may be hidden costs associated with the methods even when they are supposedly free. The fact that trialists in the interviews mentioned such additional costs, but survey respondents did not, suggest that having a chance to talk may have reminded trialists of these hidden costs. Costs varied according to the method itself and mainly related to implementation (GA, website platform feature, bespoke software, WURL), hosting on the server (GA, bespoke software, server logs, Community surveys Joomla! plugin) maintenance (bespoke software, server logs, WassUp WordPress plugin), use of software during research (website platform feature, bespoke software) and technical support (server logs, Life Guide software). One of the trialists who paid for their methods especially acknowledged that cost was a major issue which is usually underestimated in web-based interventions.

Trialists raised various additional comments at the end of the interview. Some of the comments related to the blend of technology and behaviour change and the importance of utilising the technology in the right manner.

Trialists reported the valuable experience gained from their trials will be applicable in the future when developing new web-based interventions and in informing future usage. Creating a web-based intervention is a unique experience that differs from development of interventions conducted face to face and the knowledge they gained about usage can be very applicable in the future.

Other comments related to calculating exact time on the intervention. One of the challenges with web-based intervention usage is that participants can be online on the intervention but not actively engage with it. Finding a solution to this issue can be problematic and this was discussed with the trialists. One noted that setting up a timer to log participants out after certain period of inactivity frustrated the participants. Another solution can be that, if the logging out time appears longer than a certain threshold, it can be assumed in the analyses that they had stopped using the intervention. For example, in the REACT trial if the web usage data indicated that participants were on a page for longer than 20 minutes, it was assumed that they had stopped looking at the intervention and their usage time was truncated at 20 minutes for analysis purposes (131).

Comments were also given on figuring out what to make of the usage data. Trialists find difficulties interpreting the data and trying to figure it out what is useful information from those data. As noted by trialists it can be a challenge to link the usage data with output or outcome and make meaningful interpretation of the usage data (132, 133).

Another challenge was determining engagement with web-based interventions, as the benefits of engagement may be unmeasurable using quantitative methods; for example, as explained by one trialist, one participant may only complete one module but this may be more beneficial for them than another one who completed all modules without actually engaging. One participant mentioned in particular the issue of usage with engagement related to the difference in participants' behaviour when un/supervised. Different tracking data were obtained when participants used a web-based intervention in a supervised setting versus at home. This is explored in Chapter 6 to investigate which features impact on engagement rather than just usage; this chapter explores usage and engagement with web-based interventions through focus groups discussions.

Prior to investigating engagement issues, it was decided to assess different tracking methods in order to provide recommendations to trialists. Proving this background information will benefit trialists when deciding on which tracking methods to use in the future. The evaluation, which includes amongst others, GA and server logs, as these were the most popular tracking methods, is presented in Chapter 5. The advantages and disadvantages given for each method in the present chapter will be linked to our findings in the next chapter to provide a comprehensive overview of the methods.

5.Tracking web usage

5.1 Introduction

In this chapter different tracking methods for recording user behaviour on a website are evaluated. Evaluation assesses ease of implementation of the methods, data extraction, data storage and accuracy of the tracking methods versus that expected in a controlled environment, assessing usage metrics such as page views, timestamps, logins, IP address, clicks, documents downloads and external links for a specific user. Data were simulated manually and via simulation software and data were collected from desktop clients and mobile clients. A reasoned argument of advantages and disadvantages of the tracking methods is made to act as a recommendation for trialists.

5.2 How web pages work

Websites are used to deliver feature rich material to anybody who has access to the internet, they are developed using Hypertext Mark-up Language (HTML)(134), Cascading Style Sheets (CSS) (135) and JS. In addition, websites can contain other components such as images and videos to enhance the content that they deliver. These sites are viewed in browsers and delivered to those browsers over the internet via webserver software such as Apache (136) and IIS (137) .

5.2.1 The webserver

The term webserver has two meanings:

- Hardware (a computer) that is dedicated to running the software required to handle World Wide Web (WWW) requests (138)
- Software that is designed to handle HTTP requests (139), examples include "The Apache HTTP Server Project" (136, 140) and Microsoft's Internet Information Service (IIS) (137).

A webserver requires both, hardware that is connected to a network (to enable communication between computers) and the software to deliver the different resources that make up a web page (the HTML, CSS, JS, images and multimedia).

5.2.2 Web client

A Web client (or browser) is software that is designed to collate all the resources served by a webserver and then format the display as per the instructions contained within these resources. Examples of commonly used web browsers are Google Chrome (141), Microsoft's Internet Explorer (142) and Apple's Safari (143). All browsers work in a similar way and Figure 21 shows a typical illustration of how a web browser works (144).

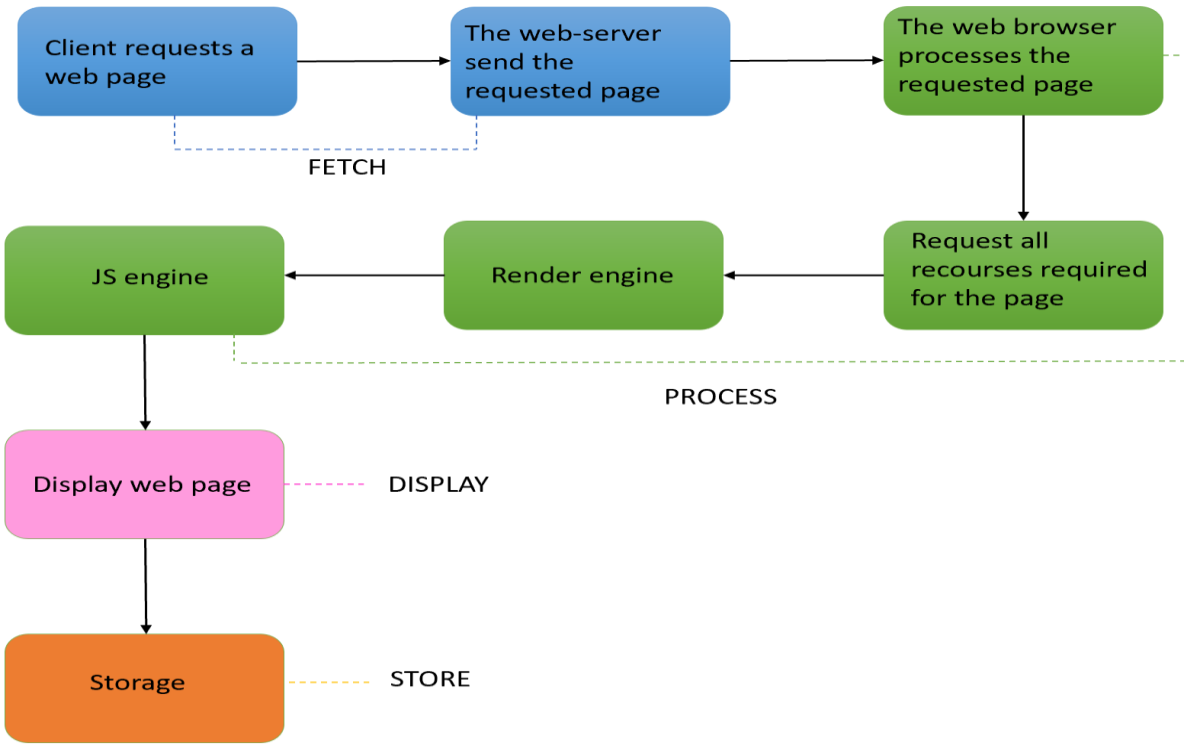


Figure 21. How a web browser works

This is highlighted using tools such as the developer tools extension within Google Chrome (145, 146) (Figure 22).

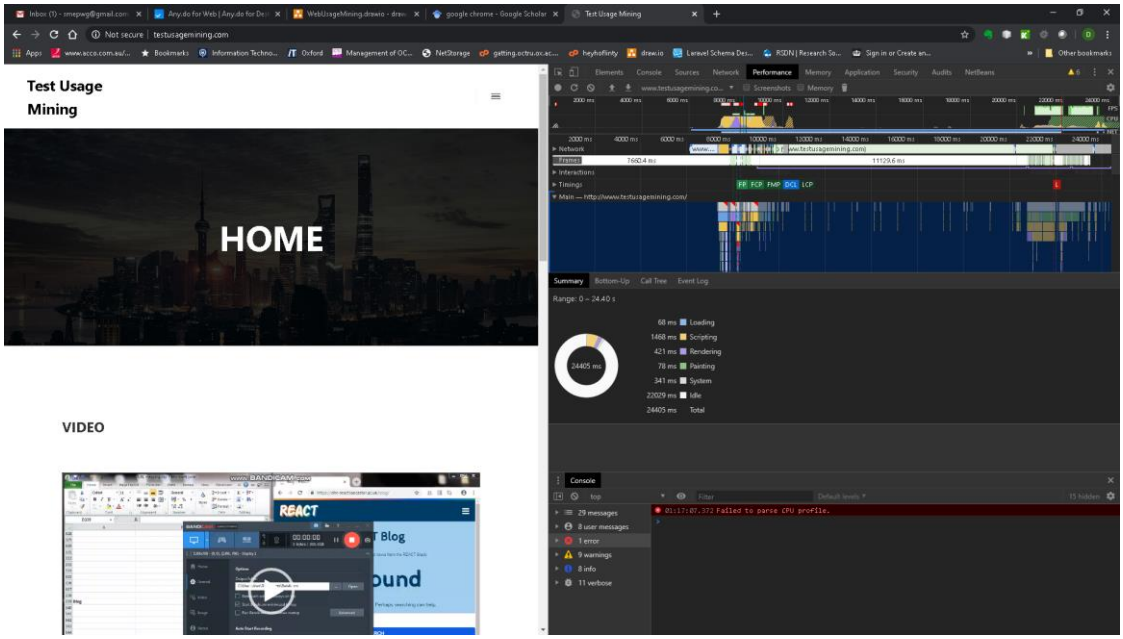


Figure 22. An example showing the time taken in the different resources required for the home page of http://www.testusagemining.com

5.2.3 The URL

Uniform Resource Locator (URL) is the complete address of a unique web resource (147, 148). Usually referred as a "web address", it consists of the domain name along with other detailed information (148). URL is a mechanism used by browsers to retrieve a specific web resource (usually a web page) (148, 149). An example of an URL would be https://www.google.co.uk, which indicates a protocol https and a domain name google.co.uk.

5.2.4 The HTTP query string

The query string is a mechanism by which information can be passed to the webserver as part of the URL, for example, the URL:
http://example.com/path/to/page?name=ferret&color=purple

Defines a request to the server "example.com", using the http protocol (150), requesting a page from "/path/to/page" with the query string "name=ferret&color=purple". The query string here is passing the parameters name and color, with the values of ferret (name) and purple (color).

5.2.5 Types of websites

Websites can be split into one of two types, static and dynamic (151). A static web page is one in which the content is stored in a text file (albeit with the extension html) and is not generated by an application running within the webserver. Pages generated by an application running in the webserver are defined as dynamic web pages (151).

5.2.5.1 Static websites

These are websites (HTML documents) that are stored as text files on a webserver, they are suitable for pages that contain information that will rarely change unless the developer makes changes (151). This is the most basic form of a website and the content on the page is more fixed, static and consistent regardless of the user (152). These pages are usually generated in a text editor such as Notepad++ (153) or an application specifically designed for creating web

pages such as Dreamweaver (154). The advantage of using specific applications is that they contain features and code snippets to facilitate the generation of web pages, the content can be pre-rendered leading to faster page speed (152).

5.2.5.2 Dynamic websites

A dynamic website is a page whose content will change, based upon the user (for example Amazon (http://amazon.co.uk) will display items on the home page based on a previous browsing history. Alternatively, the page is constantly being updated with information (for example the BBC news web site – http://news.bbc.co.uk). Websites that contain dynamic content are often database driven (155).

5.2.6 Data storage

Web browsers can store data, sometimes referred to as persistence. Examples of different storage mechanisms are shown in Table 24.

Table 24. Data storage mechanisms in web browsers

Item	Description
Cookies	Cookies are small pieces of information websites store on the computer (156, 157). This information can be stored as a file or in memory. Cookies are used to hold information that describe preferences or an identifier to tell the server who you are (156). Cookies are only shared with the server that set it. The HTTP Protocol is stateless (it does not know what has happened before), cookies can be used to access user specific data on the server and save information about the user (156). It is a requirement of the "Cookie Law" that visitors to a web site are notified of the use of cookies on the site and what those cookies are used for. Users should be asked if they are happy for cookies from the site to be used. In the UK this is enshrined in the Privacy and Electronic Communications (EC Directive) Regulations 2003 (140).
Local Storage	Stores data that does not have an expiration date in a file on the client (158). This data is not deleted when the browser is closed. Local storage is an extension of Cookies, differing in the amount of data that can be stored.

5.3 Development of the test website

A web-based intervention often comes in a format of a website containing various usage metrics. Therefore, for the purposes of our testing a test website was created that contained common usage metrics in order to mirror an example of a web-based intervention. The developed test website contained subpages, multimedia and other features such as different blocks of text in different paragraphs and external links and pdf downloads documents. It was decided that this website should include various videos and have four subpages for more detailed testing. The external links and pdf downloads were added as web-based interventions can have different guidance materials or other kind of relevant materials that can be downloaded and can include links to important health institutions or other helpful links (links to other sources or pages defined as external links). The adding of multimedia (videos) and downloads was to show the level of complexity as these metrics are complex to track.

The test website was used to mimic participants and discover navigational patterns. Then the accuracy of the tracking methods was checked and compared between the methods.

Prior to designing the website accounts, were created on YouTube (159) and Vimeo (160) platforms which are commonly used video streaming platforms and, on each platform, the same video was uploaded. A website titled www.testusagemining.com was then created to cover the different areas for review.

Three videos were added on the home page (Figure 23). The first video was hosted on the site, the second was the YouTube video and the third one was the Vimeo video. The videos were identical and only differed in the uploading method on site. The video length was 18 seconds.

The website consisted of the following four subpages: Hosted video subpage, YouTube video subpage Vimeo video subpage and Test Images subpage. The hosted video was embedded on the Hosted video subpage. The YouTube and Vimeo videos were added on the YouTube and Vimeo video subpages, respectively. The Test Images subpage was developed to include the different blocks of text in different paragraphs, had two external links (one to Google and another one to YouTube) and three pdf downloading documents.

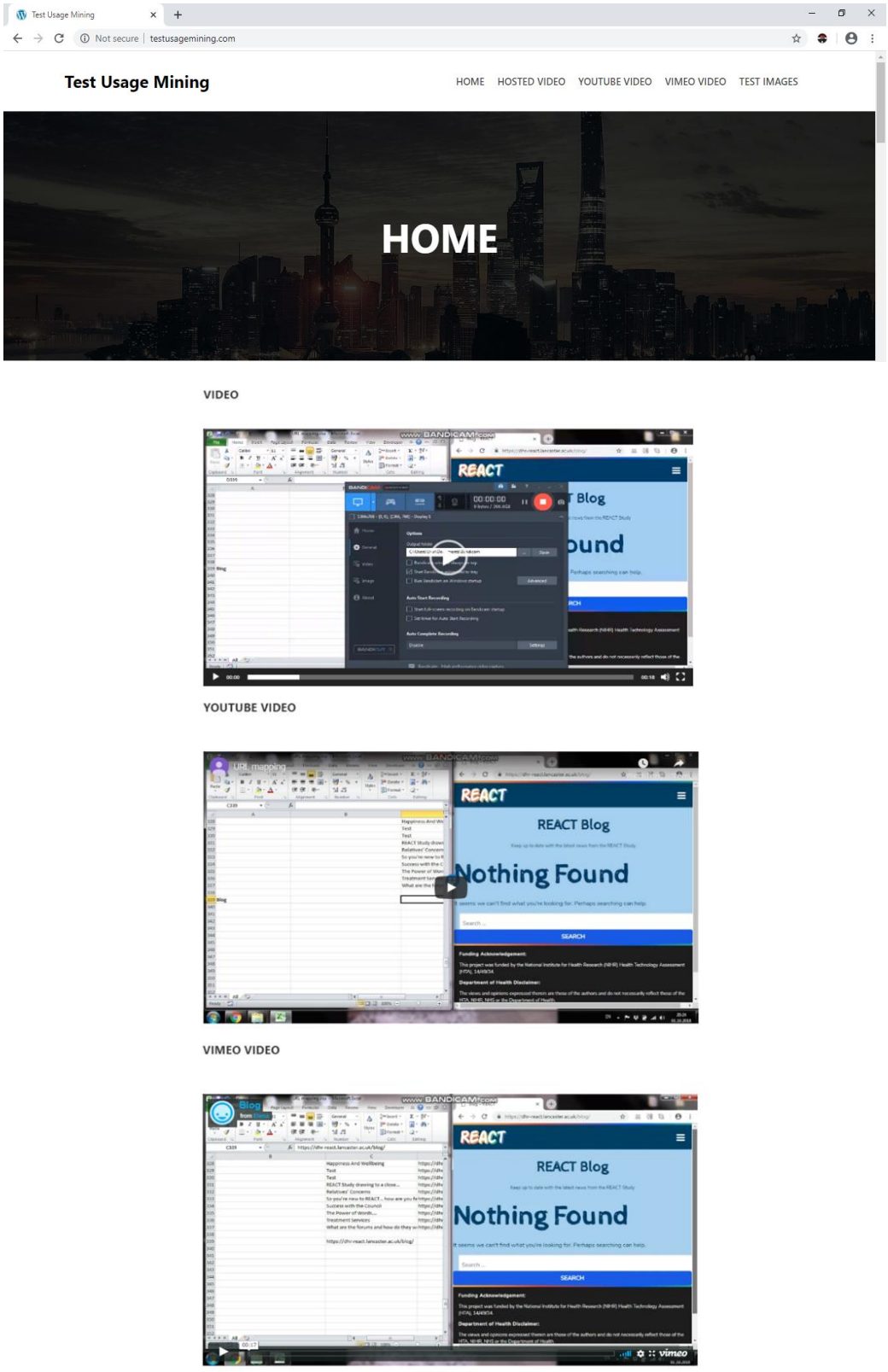


Figure 23. Index (homepage) of the website

Lastly it was checked whether the website is tablet and mobile friendly by using the WordPress (161) under Customise in Appearance feature. This gives a preview of how the website looks on desktop, tablet and a mobile device.

This website was created in WordPress version 5.2.4. A hosting account was purchased from GoDaddy.com (162)– there are many different hosting companies available to choose from. This one was chosen due to previous experience with the company and the cost being relatively low.

The option chosen was Economy Hosting with cPanel (Figure 24), this provided a graphical interface that could be used to manage the server, a domain name and backup. The hosting package chosen provided:

- 1 website
- Unmetered bandwidth
- 100 Gb Disk storage
- 512 Mb RAM
- Included domain name (testusagemining.com)

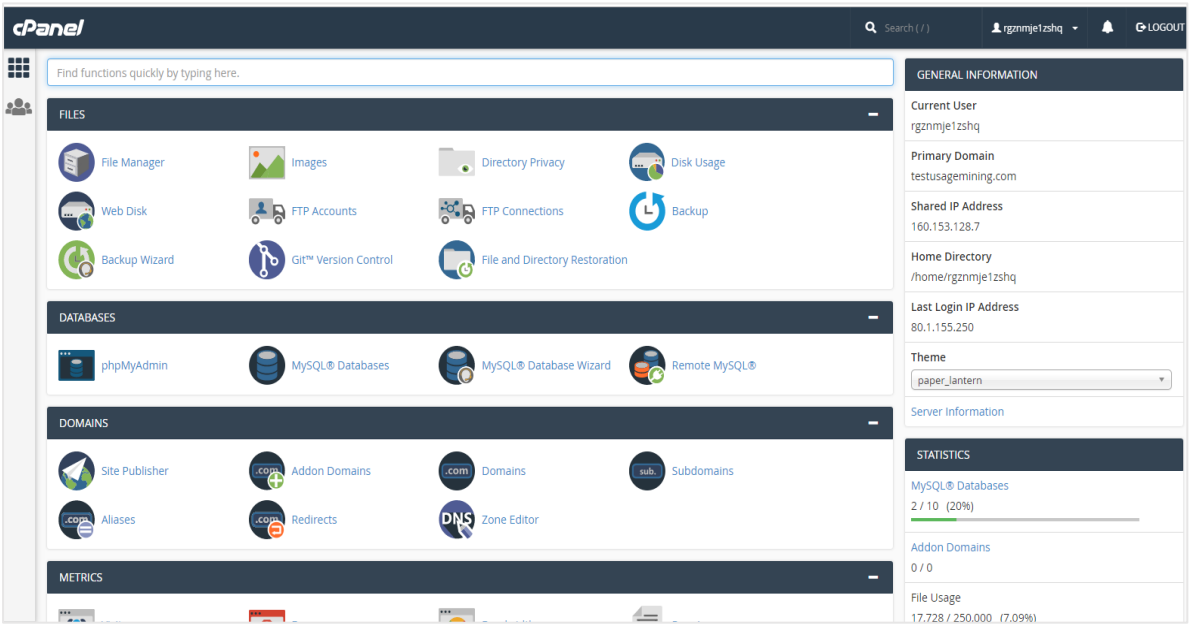


Figure 24. cPanel Interface for GoDaddy account

This is not a high-performance configuration but is enough for the requirements of this work, as it is not the responsiveness or optimisation of web pages that is being tested here.

5.4 Tracking methods for recording web usage

There are number of different methods that can be used to record how a user interacts with an intervention website, as described in previous chapters, and some of these are discussed in detail below. The tracking methods were chosen based on the methods reported in Chapters 3, 4 and 6, along with a series of Google web searches and cover hosted and self-hosted solutions to ensure a representative sample.

5.4.1 Tracking method: Server logs

Server log data were the first tracking method being evaluated and used for the comparison of the different tracking methods. The SR described in Chapter 3 found that log data was the most commonly used tracking method reported in a random sample of 100 studies, out of which 41 reported the tracking method used, eight reported using the server logs alone (19.5%) and in one study they were used along the GA method. The mixed methods study had similar results finding that server logs is a very popular method being used in five (17.8%) of the trials. The focus group study did not investigate the tracking methods used yet throughout the meetings eight out of 15 trialists (53.3%) mentioned that they have used server logs. A server log is a text file that includes information such as IP address, URL, timestamp, request, code, size, country, referrer and user agent (Figure 25). This information can later be analysed and explored to discover the user's behaviour on the website.
The different logs that are held on the webserver can be split into two types:

- Webserver logs: logs created by the webserver (referred as server logs throughout the thesis)
- Portal logs: logfiles created by code that is used to generate the content for dynamic pages.

5.4.1.1 Webserver logs

For the purposes of this work we define webserver logs as the log files that are created by the software that is used to "serve" the website content. As stated earlier, webserver logs are typically called server logs and this term is used throughout the thesis.
By default, these server logs tend to contain the following information (Table 25):

Table 25. A summary of a common variables in a server log (163)

	Item	Description
a)	Client IP Address	The IP Address of the device that requested the resource from the webserver
b)	UserID	If the user has been logged in via HTTP authentication, their username is recorded, this is not reliable.
c)	Date/Time of request	The date and time that the server finished handling the request.
d)	HTTP verb	What was the request that was made to the server, e.g. GET POST
e)	Resource	The resource requested, e.g. index.html, main.css, jQuery.js
f)	Client protocol	The protocol used to make the request, e.g. HTTP/1.0
g)	Status code	The status code of the response sent back to the client, indicating if the response was successful (150).
h)	User agent	The device/browser used to make the request

Typically, these logs are automatically created and stored on the server. Server logs are often date-stamped for ease of identification and contain list of activities of the server (121). Information about the request, including client IP address, timestamp, URL and query string, HTTP code, client protocol, and user agent, are typically added to the log server format. An example of a server log data from the Apache httpd server is shown in Figure 25.

```
95.86.41.24 - - [03/Sep/2020:02:29:22 -0700] "GET / test-images/?UserID=5&VisitedParagraphID=p3 HTTP/1.1" 200 - 14105 "http://www.testusagemining.com/test-images/" "Mozilla/5.0 (Windows NT 10.0; Win64; x64) AppleWebKit/537.36 (KHTML, like Gecko) Chrome/85.0.4183.83 Safari/537.36"
```

Figure 25. Example server log data from testusagemining.com

An IP address (164) - 95.86.41.24

User ID - 5

Timestamp - [03/Sep/2020:02:29:22 -0700]

HTTP Verb – GET

Client protocol - HTTP/1.1

URL and query string - http://www.testusagemining.com/test-images/ (subpage "Test Images")

HTTP code for the server response - 200 (200 = OK)

User agent - Mozilla/5.0 (Windows NT 10.0; Win64; x64) AppleWebKit/537.36 (KHTML, like Gecko) Chrome/85.0.4183.83 Safari/537.36

There are many different applications that can be used to summarise server logs such as Awstats (165) and Webalizer (166). These server log files are only accessible to users with access to the backend of the website (121).

5.4.1.2 Configuring and setup of server logs

This mechanism requires little or no set-up as they are often configured by default when the webserver software is installed. The choice for this project was the hosting package from GoDaddy (167) that included c-panel and access to the server log data (raw data). Since these data are immediately available the only option that was enabled in this process was to archive log files to the home directory after the system processes statistics. The system processes server logs every 24 hours and server logs for particular dates. The server logs are also archived for each month and can be downloaded for the whole month as well. Once downloaded the server logs were analysed using the Apache Logs Viewer (currently known as http Logs viewer) program (168). The use of this software assisted to ease the filter of data by an IP address and export this set of data as a separate file for analysis. The server logs usually come in a text file that consists of hundreds of rows, which was also mentioned by trialists in the mixed methods study.

"*One of the downsides is that the data is very hard to handle, like it's a huge amount of lines with so many logs and it's very hard to make, to receive meaningful measures from that.*"

P14, Interview

"*Data messy and needs to be organized by data scientist before analysis*."

P10, Questionnaire

5.4.1.3 Exporting raw data from server log data

Server log data are downloaded in the raw format so the export of raw data is completed when the log files from the system are downloaded.

5.4.1.4 Storage capabilities of server log data

Server log data can be obtained from the hosting provider for as long as the hosting package is paid for. If extended for a certain duration it will provide an access to the raw data throughout the whole duration. The server log data can easily be downloaded and saved locally for unlimited time but if the hosting package expires they no longer would be available to obtain from the hosting provider. Three trialists in the mixed methods study choose the storage capabilities of the method as one of the reasons for choosing the method and all three used server log data (one used GA in addition to the server logs).

5.4.1.5 Advantages of the server log data

Trialists in the TRACK study reported the following advantages of using the server log data - Figure 26 .

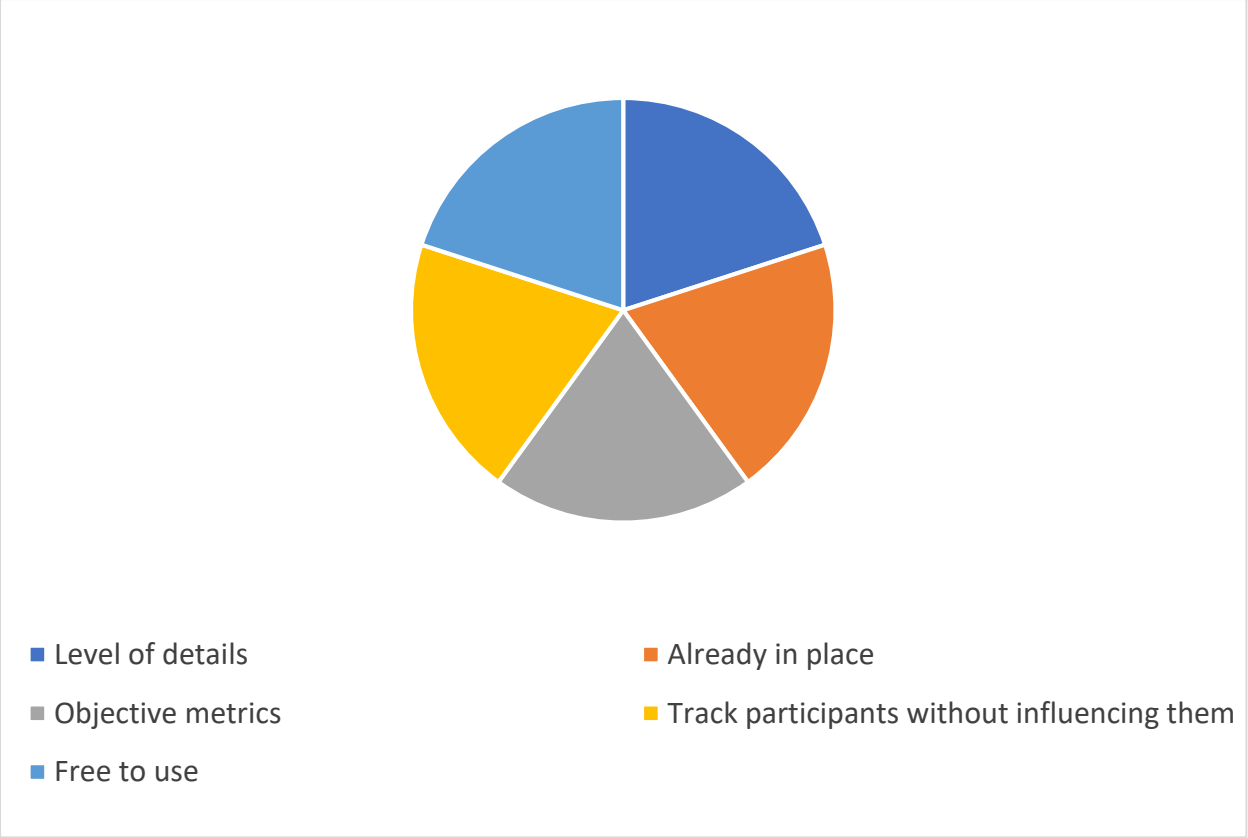


Figure 26. Advantages of server logs reported by trialists

The summary for the advantages of the server logs would be that:

- Every item that the client requests from the server is recorded
- Little or no configuration needed
- Extremely easy to extract raw data
- Data stored locally
- Time spent on all pages, but the last page can be deduced
- Free to use
- Track participants without influencing them
- GDPR complainant if configured

The General Data Protection Regulation (GDPR) compliance is important as rules with regard to collecting and use of data are highly important for web-based interventions and their tracking methods. Server logs contain IP address which can be identifiable, but they can be setup to make sure they comply with rules and regulations (169-171) .

5.4.1.6 Disadvantages of the server log data

Trialists in the TRACK study reported the following disadvantages of using the server log data - Figure 27.

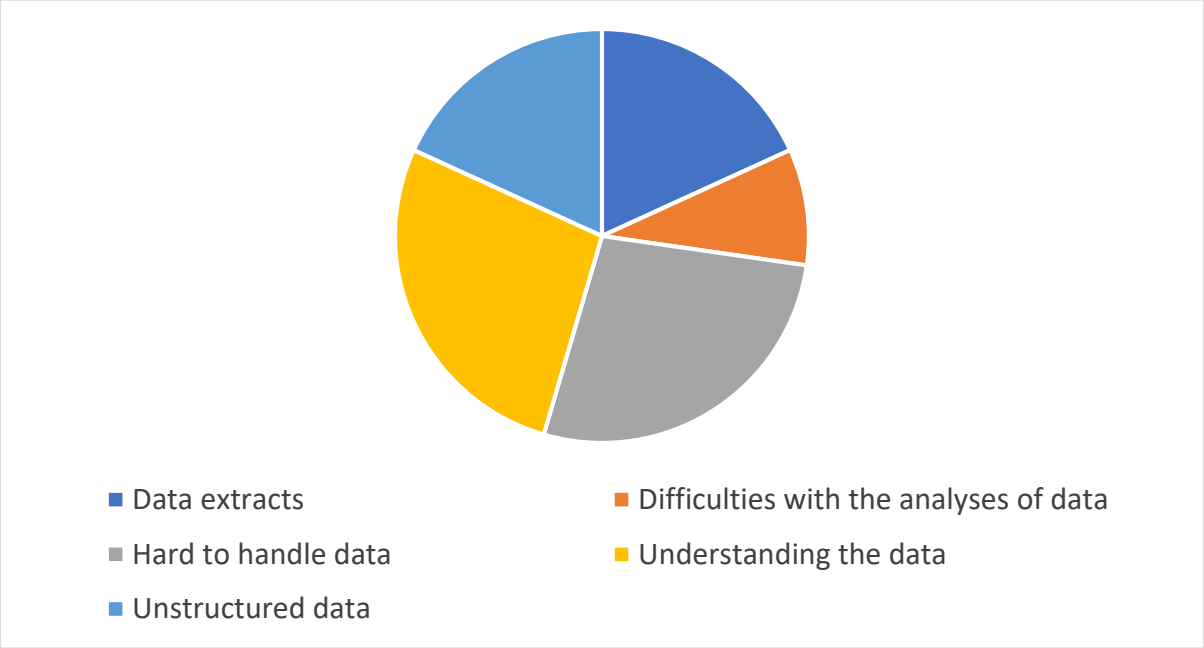


Figure 27. Disadvantages of server logs reported by trialists

The summary of the disadvantages of using server logs would be that:

- Every item that the client requests from the server is recorded
- No indication of the user accessing the page (IP Address is recorded, but if Network Address Translation is in use (many devices sharing the same external IP address) user identification is impossible). Using IP Addresses, it cannot be determined if the same user has accessed a page from home, then from work and then from an internet café). Note: If the user authenticates using BASIC authentication the username is recorded.
- Only interactions with the server are recorded, i.e, clicks on external links will not be recorded. To be able to use the server logs to store information about user activity on pages custom JS code needs to be written to ensure that this data is written to the log files (code was written to demonstrate the proof of this concept and it is described in detail in section 5.4.8.1).

• Although the extracting of the data is extremely easy a technical knowledge is required to access the server logs (for example knowledge to use the c-panel) so trialists relied on a developer hence find difficulties with the data extracts

• Difficulties with understanding and the analysis of data as they come in a file of hundreds of rows and technical knowledge is again required to understand the logs

5.4.1.7 Other logs

The use of logs was reported in 17 of the 100 studies in the SR; although server logs were used predominantly, other logs were used too. Studies reported using electronic logs, user logs, and web portal logs in the SR. In two studies, portal logs were used, three studies reported using electronic logs, and one study user logs. One study from the TRACK study reported using application logs. This section will use the term “portal log” to describe the different types of “other” log, whilst this is technically incorrect it fits with the terminology used by clinical researchers.

Portal logs differ from webserver logs in that they are generated by the applications that generate the content. As these applications have been programmed by a developer, the detail recorded is determined by the software specification (172). Typically, such logs are used to help determine what actions a user has undertaken when something goes wrong, and then to record any errors that are thrown by the software (173). These data are recorded in text files or as rows in a database table for future analysis.

As with server logs, portal logs typically contain the following information (Table 26):

Table 26. Common details stored in portal logs

	Item	**Description**
a)	Client IP Address	The IP Address of the device that requested the resource from the webserver
b)	UserId	The user identifier
c)	Date/Time of request	The date and time that the server finished handling the request.
d)	Action	What has been requested/sent to the server

5.4.1.8 Advantages of portal logs

The advantages of portal logs are:

- The developer has control over what is stored and to some extent where and for how long
- If a study participant logs into the intervention website, all requests can be associated with that participant.
- These logs may be more accessible to the research team as server logs may be deleted after a set period due to GDPR constraints

5.4.1.9 Disadvantages of portal logs

The disadvantages of portal logs are:

- Developer time is needed to write and test the implementation.
- Only interactions with the server are recorded, unless there is custom JS written that then sends data back to the server to be stored with other data.

5.4.2 Tracking method: Google Analytics

GA, used by around 30 million websites is the most popular method in this field (174-178) and it was chosen to be used in the evaluation of the tracking methods. In the SR in five studies 12.2% this method was stated to be used. GA was the mostly reported method to be used in the mixed methods study by seven trialists 25% and three out of 15 trialists in the focus group study reported using it although questions about the type of tracking methods used were not asked in these meetings.

This web analytics tool was used for free. The advanced Google Analytics 360 version had additional premium features and it was considered to be used at the begging of the project in 2019. The request was rejected by the Google Marketing Team (179) explaining that the advanced program starts at price of $150.000 and it can only be used for existing business that can commit to a certain media spend. Based on this and the fact that this website was for testing purposes only the Google Analytics 360 was dismissed, and it was proceeded with the thorough examination and testing of GA only.

GA was introduced on the 14th of November 2005 (180, 181). A new and improved version was released in October 2012 which was called Universal Analytics that introduced the Google Tag Manager (180). The latest version is GA 4 available from October 2020 (180).

The project started with examination of GA to show that this version does not provide the level of detail of tracking usage data required. This version gives data for pageviews without proving exact time and uniquely identifying users. Therefore, the upgraded version of Universal Analytics with the use of Google Tag Manager was implemented and used to examine and evaluate. This advanced version of Google Analytics introduces new features such as new tracking code, custom dimensions and metrics, data integration (13, 14) and, most importantly, has the ability to uniquely identify users (introduced in Chapter 2 and described in detail in section 5.4.5), as trialists conducting web-based intervention are interested in tracking participants individually. Although aggregated data can provide useful information (such as most frequently visited modules, most common time of access etc.) this is not sufficient information, as discussed by trialists in interviews and described in detail in section 5.4.5.

"I don't know, it's been a while since I've spoken to a programmer about Google Analytics but from previous conversations I know that Google doesn't really like you to track individuals and they put some barriers in place but there are ways around them."

P2, Interview

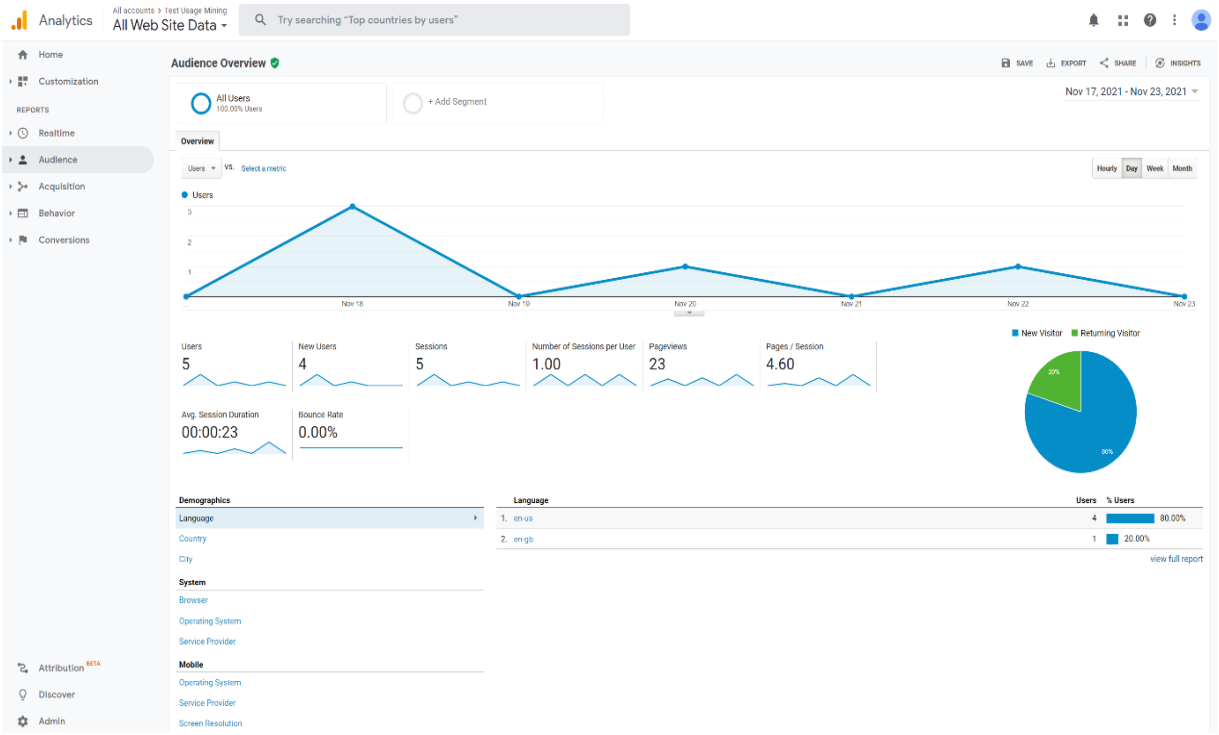


Figure 28. Google Analytics Dashboard

5.4.2.1 Configuring and setup of Google Analytics and Universal Analytics

To configure GA, an account was created on their official site analytics.google.com using a Gmail account. After setting up basic configuration details, a unique tracking code was then available, and this code was added on the website. The code links the website with the account, and it was implemented via WordPress plugin called WP (GADWP) (182). The reason for installing this plugin was the ease of installation and automatically adding the code to all subpages as well as the fact that the code does not to be added if a theme is switched in WordPress.

This plugin came with a mini dashboard in WordPress giving general tracking information and statistics but it was not as detailed as the GA dashboard itself, so it was not used in the research. The dashboard in GA (Figure 28) continued to be used as it provided more advanced and detailed outlook.

In configuring this method, it was checked to see if there are sampled data used in their reports. Sampled data refers to the extraction of a subset of the website data (183). One way of checking for non-sampled report is if there is a green shield icon with checkmark at the top

of a report which was exactly what was shown on reports (184). Also, sampling can occur when a request is made for a report that is not pre-aggregated and the number of sessions in data is over 500,000 (185). This large number of sessions was not characteristic for this research since the number of sessions from the test page was way below this number and there was a green shield icon on the reports, so the conclusion was that the GA reports had not been generated using sampled data.

When implementing Universal Analytics, a new tracking code on site was added and no further configuration was required. The same Dashboard in GA and account were used whilst using the new improved features.

5.4.2.2 Exporting raw data from Google Analytics / Universal Analytics

To export raw data from GA, the R program and the R studio (186) were used. R is a programming language and a powerful tool for analysing data which easily accesses the Google Analytics' API (Application Programming Interface – software interface that connects two applications (187)). After enabling the GA API and downloading the programs the next step was to download a package for accessing the API. Once completed the following code below was ran with changes appropriate to the right parameters needed. Using R and R studio the raw data from Google Analytics and later Universal Analytics were also exported.

```
library(rga)
rga.open(instance = "ga")
ga$getData(id)
gaData <- ga$getData(id, batch = TRUE, start.date = as.Date("2019-07-03"),
                     end.date=as.Date("2019-08-27"), metrics =
"ga:pageviews,ga:entrances,ga:sessions, ga:timeOnPage",
                     dimensions = "ga:date,ga:hour,ga:minute,ga:pagePath,ga:previousPagePath
")
#write to csv file called My Data Export
write.csv(gaData, "My Data Export.csv")
```

Exporting raw data showed that the accessed pages' and subpages' paths were ordered in a non-sequential way. Several times data were exported and the page paths of each user examined. With further investigation it was determined that the order of page paths depends on the order of all dimensions in the code. After re-arranging the dimensions, it was possible to obtain the page paths in the right order. So, the finding from this was that the order of all dimensions in the code for the R program influences the sequential order of actions.

5.4.2.3 Storage capabilities of Google Analytics and Universal Analytics

Based on information online (188) and on the Support Google Analytics page (189) there is a new setting in Analytics called Data Retention. That means that by default, Google will set the User and Event data to expire in 26 months unless set up differently. There is also "Do not automatically expire" option which was chosen for our data. That means that data can be stored for unlimited time.

5.4.2.4 Other features and functionalities of Google Analytics/Universal Analytics and Google Tag Manager

Some of the common features in GA/Universal Analytics are filters, campaign tracking, site search, event tracking, Google Analytics Add-Ons, keyword referrals, enhance e-commerce, GA API, custom metrics and dimensions, real-time reporting (190, 191). GA/Universal Analytics had plenty of features applicable and fit for marketing purposes but also lots of its features can be used in clinical trials and more specifically in web-based interventions. For example, a feature such filters are useful as they help to filter only relevant data and event tracking as well as pageviews and events are great foundation of many reports in GA.
Google Analytics/Universal Analytics also introduced real-time reporting which can be useful to track current activities on site (115).
Very important features to note are custom metrics and dimensions that help extracting raw data. Data can be exported in csv and excel format easily from the Dashboard but for extracting raw data these predefined metrics and dimensions are used. These are essential when creating custom reports and by picking the desired dimensions and metrics a custom

report is created. For the purpose of the testing, new dimensions were created to enable exporting all relevant data needed so this feature was greatly used by the author.

The way GA/Universal Analytics is tracking the user interactions is by adding tracking code the website (explained in section 5.4.2.1). For tracking events that are not just pageviews a GA/Universal Analytics can be used in conjunction with Google Tag Manager (117, 192). Google Tag Manager does not replace GA but enhances the number of usage metrics that can be tracked, allowing more detailed tracking (193). The process of the configuration of some of these events is described in section 5.4.8.2 but it is important to note that other events can be tracked too.

Google Tag Manager is a free tool by Google, used to insert tracking or conversion code (tags) into a webpage (117, 193). Example of such tags include GA Universal Analytics tracking code, AdWords remarketing code, heatmap tracking code (192). It also includes a set of pre-baked custom code from third party companies that integrate very well with webpages. Google Tag Manager is generally used by marketers, web designers and developers, data analysts and content owners (192). This tool is different from GA/Universal Analytics. Google Tag Manager is used for storing and managing third party code, there are no reports and no analysis can be made here (193). Unlike Google Tag Manager, Google Analytics/Universal Analytics is used exactly for that purpose, reporting and analysis. Therefore, both of them were used to enable tracking desired events in the testing process.

The GA is currently non-compliant with GDPR (194, 195).

5.4.2.5 Advantages of Google Analytics/ Universal Analytics

Trialists in the TRACK study reported the following advantages of using Google Analytics - Figure 29.

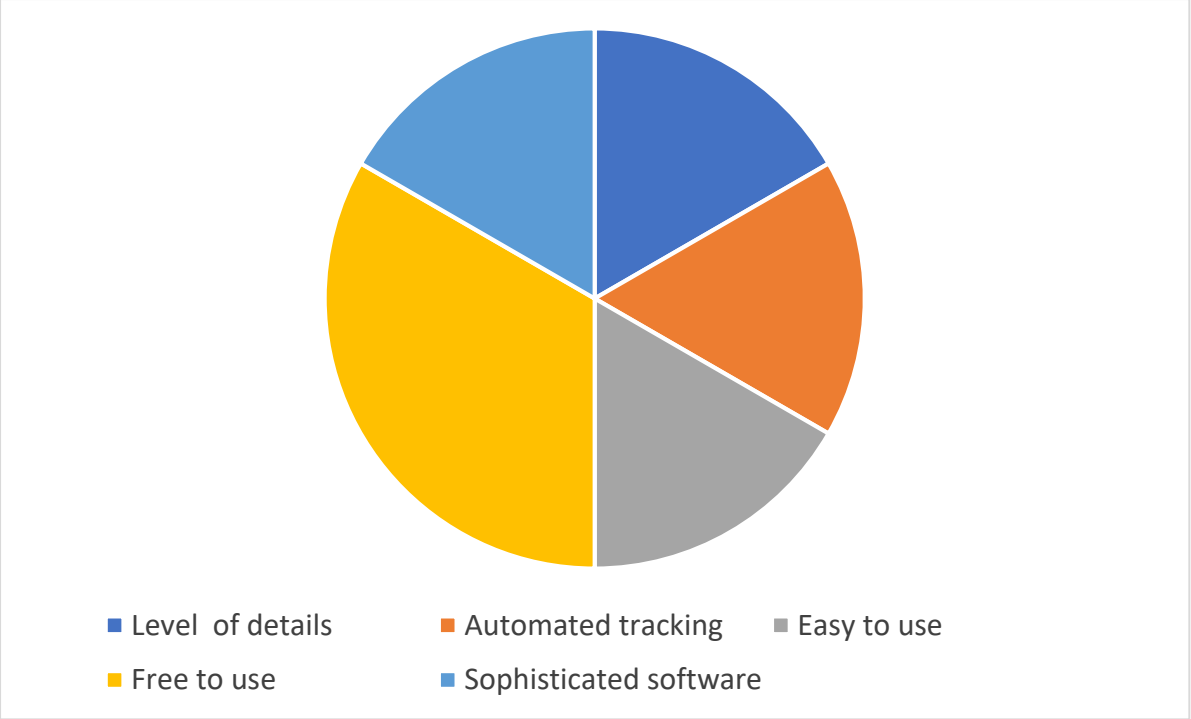


Figure 29. Advantages of Google Analytics reported by trialists

The summary of the advantages using Google Analytics/Universal Analytics would be:

- Friendly dashboard
- Level of details
- Additional features available
- Well-known software
- Track participants without influencing them
- Unlimited data storage
- Free to use

5.4.2.6 Disadvantages of Google Analytics/ Universal Analytics

Disadvantages noted in the TRACK study are given in the Figure 30 below.

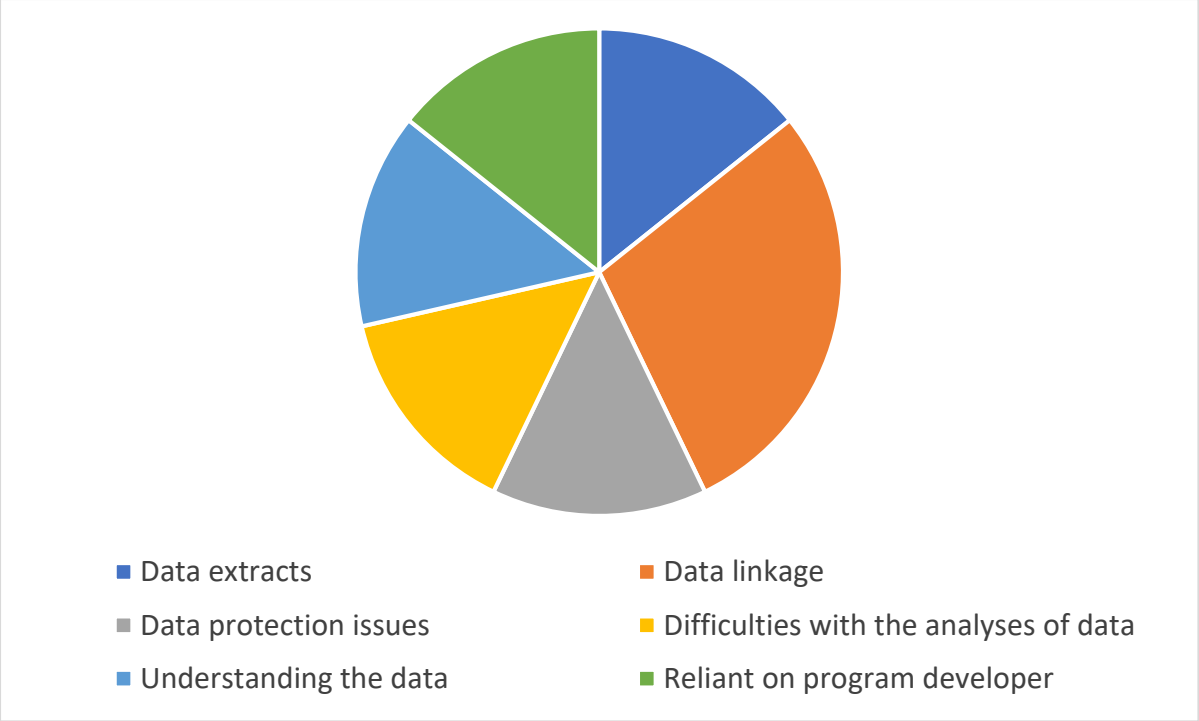


Figure 30. Disadvantages of Google Analytics reported by trialists

So, overall disadvantages of GA would be:

- Technical knowledge required for configuration
- Technical knowledge required to uniquely identify users (Data linkage)
- Technical knowledge required to extract data
- Reliant on program developer
- GDPR non-compatible

Several comments were made from trialists in the projects with regards to the disadvantage of the need for technical assistance to uniquely identify users.

P3, Focus group 4

"So, the disadvantages are that your programmer still needs to do stuff to make sure Google is tracking your website and that they need to use some clever tricks to make sure it's tracking individuals and not groups. "

P2, Interview

“Because it was quite confusing as to how to get the data for each participant, because I wanted to know how many times each participant had visited the website and how many times or at how long each participant spent on the website and it was hard to get that data from Google Analytics. “

P5, Interview

As the GA is not GDPR compatible one trialist made the following comments with regards to the privacy of data and this tracking method.

“*We did not want to use google analytics for registered participants during their study participation as of data protection issues*.”

P2, Questionnaire

Two trialists made comments on the reliability of this method.

“We sort of use, we captured the website analytics from Google Analytics and the monster insights plugin because that could kind of track across multiple devices, but it didn't always, it wasn't a 100% fool proof so sometimes for some reason he looks like the person hasn't actually engaged, but when you speak to them, they certainly have been. So, that yeah, I think that's not 100%.”

P3, Focus group 3

“I can say absolutely the same. I think that's the biggest issue with ours is because we've used, we're very lucky that we've got a tool that we can design the websites with and we can collect a lot of the usage metrics behind that but because of the way it was setting up, we ran originally on Google Analytics and then for the RCT we tied up to Matomo and even though the person who does all of our technical stuff is hugely experienced it's been a real eye opener because we're all used to using our Life Guide system, and so, when I get I mean the metrics I get from that are pretty horrific because they're kind of for data sheets of it, but I know what's

in there and I know how to put it together but yeah Matomo Google Analytics we're a bit I guess, I just worry because, depending on how you cut the data you get different answers which makes you feel like there's something not quite right there."

P4, Focus group 3

5.4.3 Tracking method: JavaScript trackers

Many JS trackers are available to be used for website tracking and the following were chosen for the purposes of the thesis: Open Web Analytics (49), Matomo (50) and Amplitude (51). These three are amongst the most popular website analytics tools (176, 196, 197). Open Web Analytics is a self-hosted tool with similar capabilities to GA. Matomo allows tracking of the users' journey on a site, giving users ownership of the data and focusing on privacy protection of users (175). This tracking method was reported to be used by some trialists in the focus group study. Amplitude is a web analytics platform that focuses on tracking user experience and user behaviour (177).

5.4.3.1 JavaScript tracking method: Open Web Analytics

Open Web Analytics is a real-time tracker and data are immediately available after installing. This tracker comes with a very friendly user interface and easy access to reports and visit details. The Open Web Analytics Dashboard (Figure 31) consists of the following sections: Content, Action Tracking, Visitors, Traffic and Goals. A date range can be easily selected and each visit log is shown clearly stating browser type, pages viewed and visit length. Filtering by IP address is also possible.

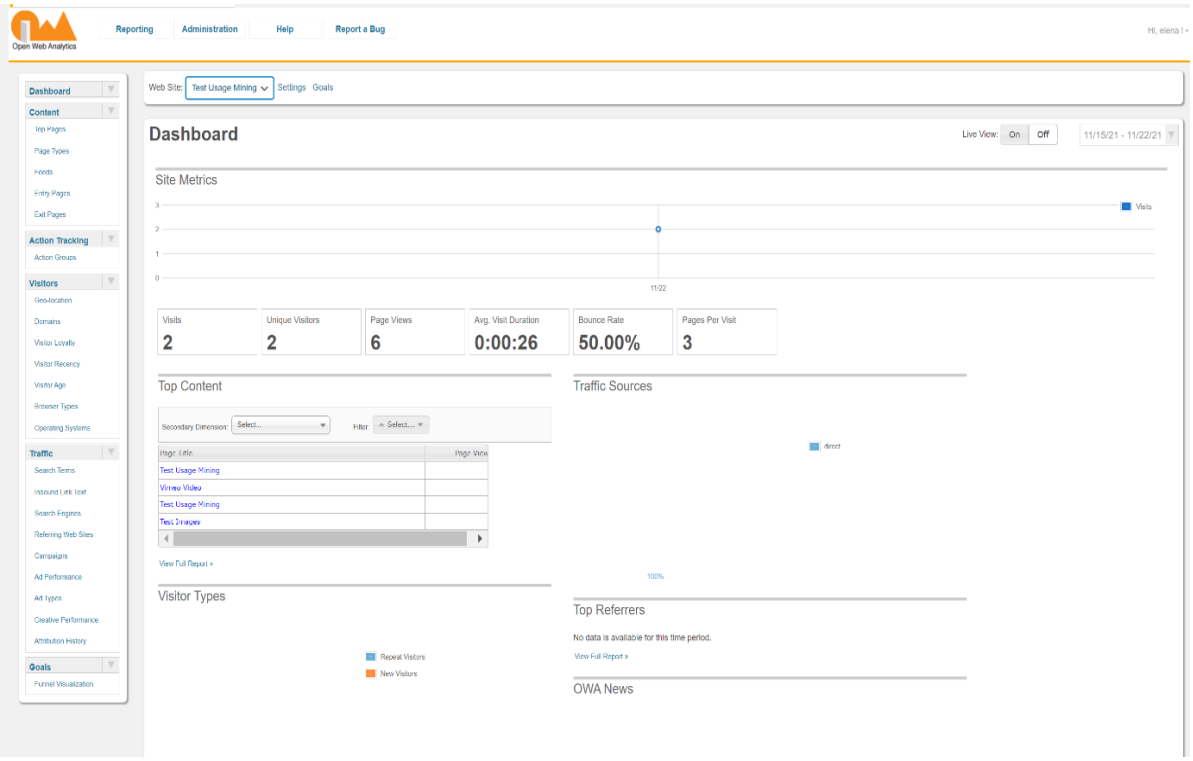


Figure 31. Open Web Analytics Dashboard

5.4.3.2 Configuring and setup of Open Web Analytics

This tracker was installed on the server and the plugin was installed in WordPress. The theme compatibility was checked by finding the suggested line <?php wp_footer(); ?> in the body tag in the footer.php template. The tracking code obtained from OWA (198) was added to the body <> of the site on all pages.

```
<!-- Start Open Web Analytics Tracker -->
<script type="text/javascript">
//<![CDATA[
var owa_baseUrl = 'http://www.testusagemining.com/wp-content/plugins/owa/';
var owa_cmds = owa_cmds || [];
owa_cmds.push(['setApiEndpoint',
'http://www.testusagemining.com/index.php?owa_apiAction']);
owa_cmds.push(['setSiteId', '4e59f4f39f16d72463bd5b278f55bccb']);
owa_cmds.push(['trackPageView']);
owa_cmds.push(['trackClicks']);
(function() {
        var _owa = document.createElement('script'); _owa.type = 'text/javascript'; _owa.async
= true;
        owa_baseUrl = ('https:' == document.location.protocol ? window.owa_baseSecUrl ||
owa_baseUrl.replace(/http:/, 'https:') : owa_baseUrl );
        _owa.src = owa_baseUrl + 'modules/base/js/owa.tracker-combined-min.js';
        var _owa_s = document.getElementsByTagName('script')[0];
_owa_s.parentNode.insertBefore(_owa, _owa_s);
}());
//]]>
</script>
<!-- End Open Web Analytics Code -->
```

5.4.3.3 Exporting raw data from Open Web Analytics

The export of raw data presented an issue with this tracker. At the outset no data export is available through user interface and data needs to be exported via data access API. The data access API can be accessed via REST request or the PHP method getResultSet and the instructions are given on the Open Web Analytics website (49). That means that developers'

at least moderate knowledge in programming is required to perform this task. The Open Web Analytics original code was altered and adjusted for the website (via REST).

http://www.testusagemining.com/wp-content/plugins/owa/api.php

?owa_apiKey=[redacted]

&owa_do=getResultSet

&owa_metrics=visitDuration,visits,pageViews,pagesPerVisit,repeatVisitors,visitors,bounces

&owa_dimensions=date,day,browserType,country

&owa_startDate=20190918

&owa_endDate=20191001

&owa_limit=1000

&owa_siteId=[redacted]

&owa_format=xml

5.4.3.4 Storage capabilities of Open Web Analytics

One of the Open Web Analytics advantages is the ownership of own data so data are stored on own server and can be kept for an unlimited time (199).

5.4.3.5 Other features and functionalities of Open Web Analytics

Important features in Open Web Analytics are DomClicks or mouse clicks and DomStreams or mouse recordings. As Open Web Analytics' developers describe it the best way to look at mouse tracking is like a one-way mirror through which can be seen how users interact with the page (200). Mouse recordings can answer plenty of important questions, for example, if users are scrolling down the page and to what extent, if users click on a specific element of the page or if users use any keyboard shortcuts to navigate the page. Since Open Web Analytics is a free open source software there is no limit on DomStreams. To enable this a code was adjusted and added to the site which made the mouse recordings available. The Figure 32 shows how a recording looks like.

Another important feature in Open Web Analytics is the Heatmap Overlay feature which is setup by default. This tracker uses HTML 5's canvas to paint heatmaps over the webpage (49) to show users' activity on site. By clicking on the start button, it shows where the users are most engaging on the webpage (for example how far they scroll, which videos are viewing, which subpages are opening the most).

With regards to the GDPR, changes to the master of OWA brought this tracker into closer alignment with OWA (201). As explained by the developer OWA respects donottrack property that can be set by users in their browsers and suggests not logging user names and email and anonymising IP addresses (201). So, overall if setup correctly this tracker complies with the GDPR rules.

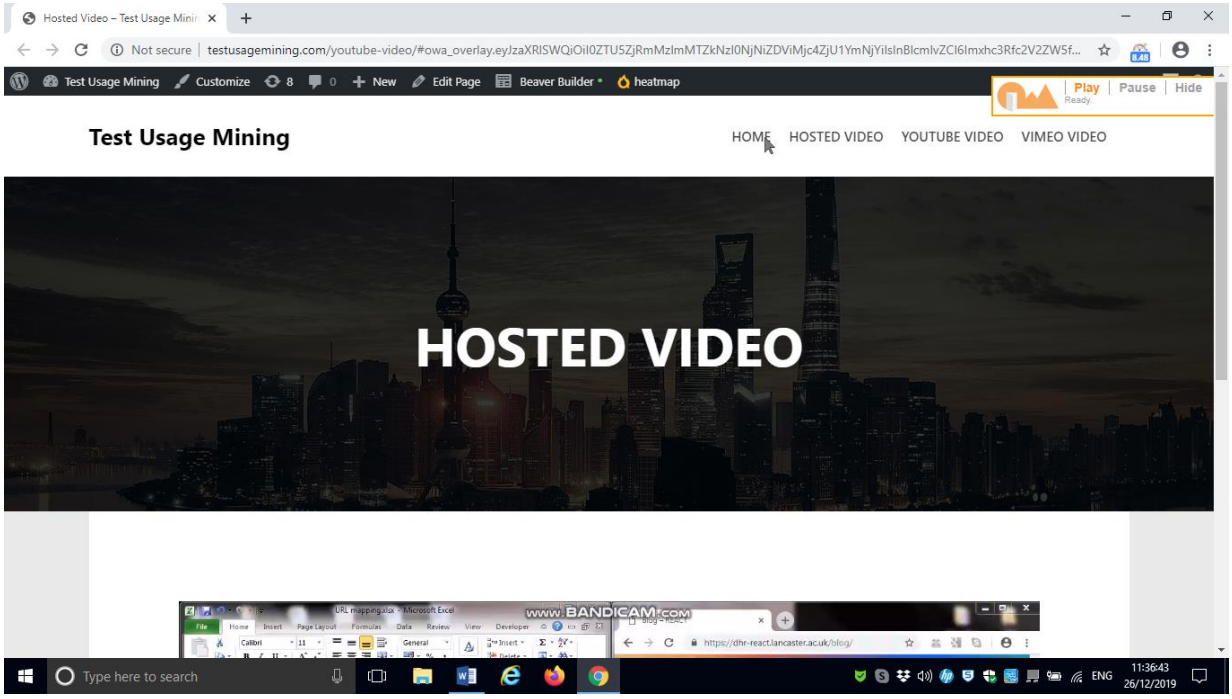


Figure 32. A recording of DomStreams in Open Web Analytics

5.4.3.6 Advantages of Open Web Analytics

The following advantages can be summarised for Open Web Analytics:

- Friendly dashboard
- Easy access to reports

- Additional features available (embedded features as Heatmap Overlay, Domstreams and Dom Clicks)
- Data stored locally
- Track participants without influencing them
- Unlimited data storage
- Free to use
- GDPR complainant if configured

5.4.3.7 Disadvantages of Open Web Analytics

The disadvantages of Open Web Analytics are as follows:

- Technical knowledge required for configuration
- Technical knowledge required to uniquely identify users
- Technical knowledge required to extract data
- Technical knowledge for implementing various features

5.4.3.8 JavaScript tracking method: Matomo

Matomo (formerly known as Piwik) was another JS tracker that was used. This tracker has premium and free versions, premium version including more upgraded features. Matomo is another real-time tracker so data are immediately available after installing. This tracker has very friendly user interface and a clean and organised dashboard- Figure 33. The Matomo Dashboard consists of the following sections: Visitors, Behaviour, Acquisition, Goals and Marketplace. Visits in Real time are nicely presented and a specific date range can be selected. Visit details provides extensive amount of data including Operating System and details about the device (type, brand, model and resolution).

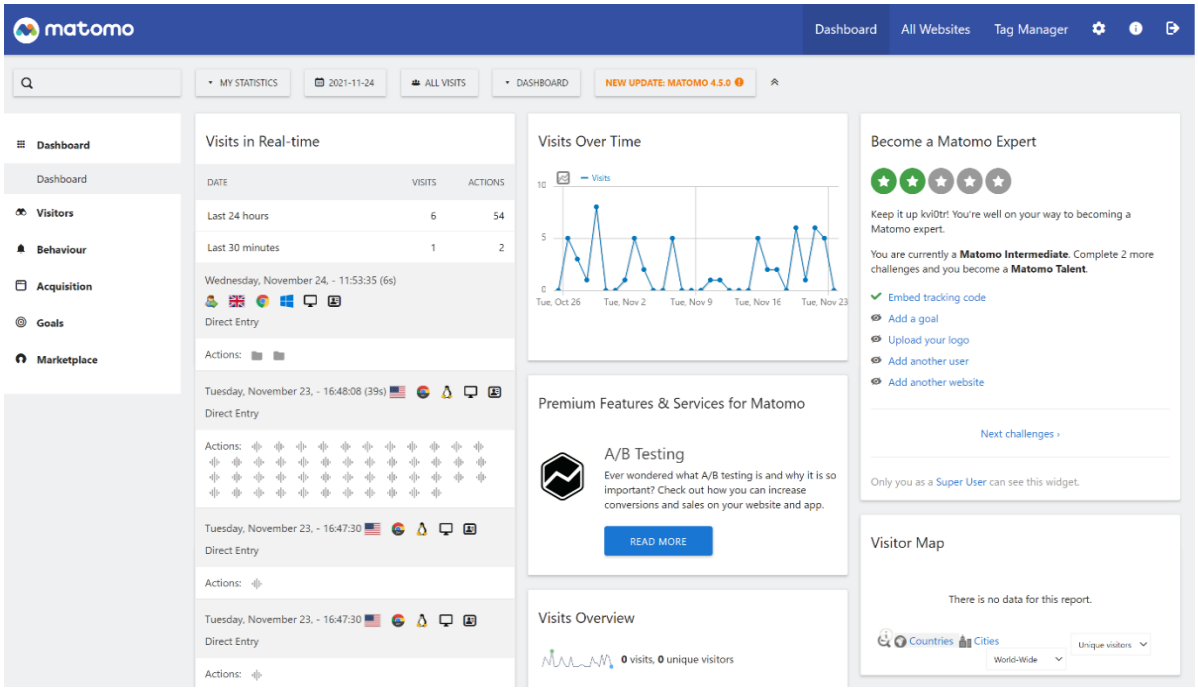


Figure 33. Matomo Dashboard

5.4.3.9 Configuring and setup of Matomo

For the purpose of this project this tracker was installed on the webserver through the c-panel for free. While installing Matomo no major issues or difficulties were present. With the installation of Matomo a new app was shown on c-panel under Installatron and the Matomo Dashboard was immediately available.

5.4.3.10 Exporting raw data in Matomo

Raw data from Matomo can be easily exported and selecting the right type of report can include all relevant data needed. Data for each visit log were exported in a TSV (Excel) file for clearer representation of data but can also be exported in other formats. When exporting data is it important to note that Matomo generates by default a Visitor ID to distinguish users. Later in the data simulation testing process when the User ID was enabled it was confirmed that the new exported raw data included the User ID column too. Something else to also note is the format of exported raw data. The format of the data is wide which makes it more difficult for use in analyses. For tasks such as investigating interactions and more specifically

users' paths, the data in this format are extremely difficult to read and follow. To overcome this, the format of the csv file was reshaped from wide to long using the STATA (202) program.

5.4.3.11 Storage capabilities of Matomo

Similar to Open Web Analytics, Matomo also gives ownership of data when the tracker is installed on one's own server meaning that they do not have control over it. The installed version on server was Matomo On-Premise and a member of the Matomo team (203) confirmed the same that Matomo On-Premise allows data to stay on server unless data are deleted.

5.4.3.12 Other features and functionalities of Matomo

Matomo includes many features but they differentiate based on the type of the Matomo version used (204). Tracking video and audio players are available in the premium versions and although for this testing this was enabled by adding code on the site these features can be immediately available if premium versions are used. This tracker also characterises with real time data updates, customisable dashboard, custom dimensions and additional features fit for marketing purposes (204). Other features included in the premium versions of Matomo are custom reports, A/B testing platform, session recording and a feature that can definitely be used for web-based interventions: a Heatmap Analytics (204). With the Heatmap Analytics feature heatmaps, scroll maps and clicks of users are displayed in overlay Heatmap reports. Heatmaps Analytics is not included in Matomo's essential plan but is included in the other premium versions (business and enterprise).
Another feature to be highlighted and which is included in all versions of Matomo is the GDPR manager (50, 205). This enables by default to be compliant with the GDPR guidelines (205).

5.4.3.13 Advantages of Matomo

The following advantages can be summarised for Matomo:

- Friendly dashboard
- Additional features available (premium version includes Heatmap Analytics feature)
- Easy access to reports

- Data stored locally
- Unlimited data storage
- Track participants without influencing them
- Free to use
- GDPR complainant (configured automatically)

5.4.3.14 Disadvantages of Matomo

The only disadvantage of Matomo stated by one trialist in the focus group study it was that they could not download a large amount of data from Matomo. However, given that the developer is in control of the server the data can be potentially extracted in a different way.

"We set up a Matomo as well to run alongside it along with a unique identifier that was linked up then to the data we were collecting, the behavioural data that we were collecting as part of the site. So, the intervention was kind of like hand washing and other infection control behaviours in the home, so there were sections where people could fill in kind of what they were doing and make a plan of what they were going to do. So, we generated a kind of a 16-digit randomised string but then was also linked up to the Matomo usage data, so we could track, combine the usage data there with the behavioural data. So, we were looking at very similar things kind of number of logins, average usage time, sections of the site they've used. We also to make it a little bit quicker and easier for the key things we were wanting to look at put in actual variables logged in the database. So, primarily start and finish of key sections of the website so when they hit those pages it did a date timestamp directly into the database which allowed us to quite quickly just for those kind of that very broad spectrum of know how many people started these sections and how many people finished them, what was the average time of completion for those sections meant we didn't have to dig through the often quite overwhelmingly large amounts of data as I think we had nearly 200,000 people using the site by the time we were looking at the data. So, pulling off all of that from the analytics data when you have every page logged, where at one point the data set was so large the web-based Matomo system wouldn't let me download them. I had to go back in through the database to actually extract and it kept crashing the web front side of it. So, for those kinds of

more broad no for those less detailed bits we used stuff directly from the database, so we kind of had a bit of a layered approach for that."

P3, Focus group 4

So, the disadvantages of Matomo would be that:

- Technical knowledge required for configuration
- Technical knowledge required to uniquely identify users
- Technical knowledge required to extract data (potential issue with extracting large data)

5.4.3.15 JavaScript tracking method: Amplitude

Amplitude is also a real-time tracker and has a Dashboard (Figure 34) that includes the following main sections: My Workspace, Notifications, User Look- Up, Releases, Spaces, Govern, Data Sources, Data Destinations, Settings. There is also a "New" button that includes Chart, User Cohort and Dashboard. Under the "Chart" more options are available for analysis of data. More chart types are available in this section and for this research User Sessions were often used. User sessions chart gives details for each visit made by users on site and a date range can also be selected.

5.4.3.16 Configuring and setup of Amplitude

The first two steps of installing this tracker were straightforward so a project titled Test Usage Mining was initially created and then on every page a code snippet obtained from the Amplitude site was pasted before the </head> tag.

The final step of the process was to add a line of JS code to send an event to the Amplitude server. Once this was completed it was then possible for events to be send to Amplitude and to create a Dashboard (Figure 34).

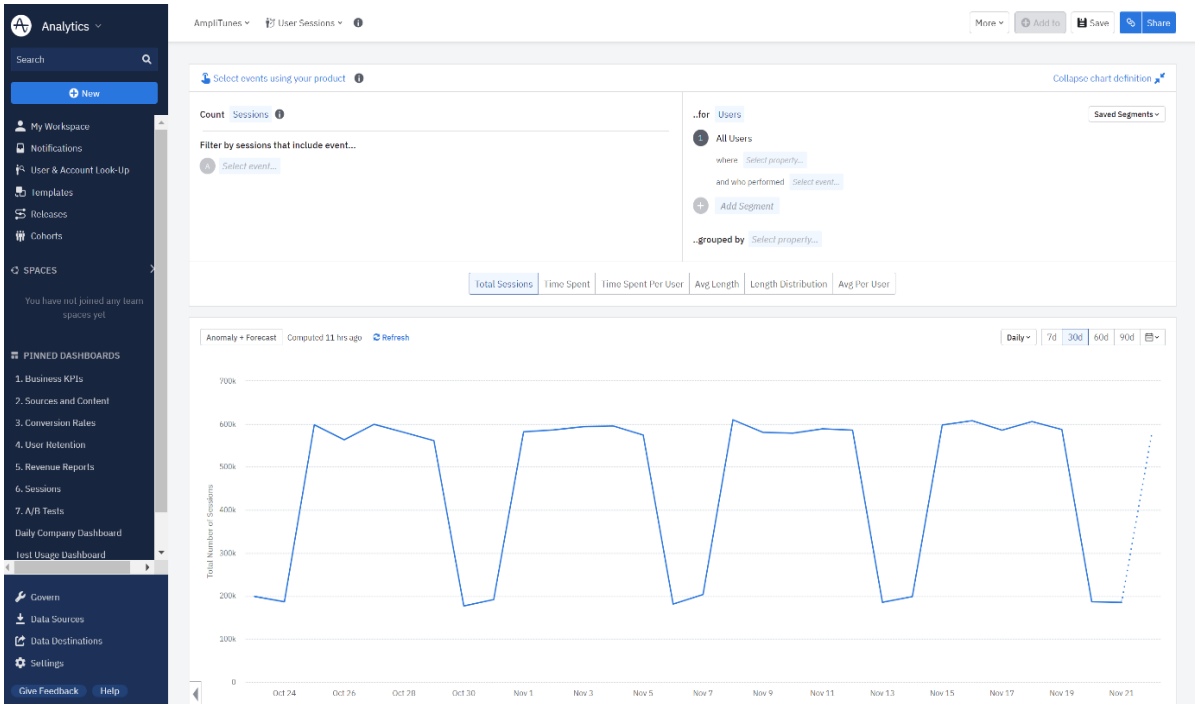


Figure 34. Amplitude Dashboard

5.4.3.17 Exporting raw data from Amplitude

Amplitude has a simple way of exporting raw data. A specific date range can be selected and the results are returned as a zipped archive of JSON files. Once downloaded they were converted to csv files ready for analyses. Amplitude points out that while exporting raw data few things should be considered. The first one is that the specified data range is the time of when the event data was uploaded to Amplitude servers. Next, the export API is not supported for a cross-project view because the view does not own any data and finally the size limits is 4GB.

5.4.3.18 Storage capabilities of Amplitude

Based on a private conversation with a Product Analytics Consultant (206) from the Amplitude Support team the information for the storage of data in Amplitude is that all data is stored for an unlimited time unless requested deletion of the project (or deletion of a specific user).

5.4.3.19 Other features and functionalities of Amplitude

In Amplitude as part of the chart menu there is event segmentation, funnel analysis, retention analysis, and user composition which indicates that different analyses can be performed by selecting the desirable events (51). All these analyses can be used for clinical purposes depending on the data that needs to be analysed.

Other features that definitely can be useful for web-based interventions are behavioural cohorts and custom formulas. Behavioural cohorts allow to create a custom definition of a group of users based on the events or sequence of events they have performed. Cohorts can be created based on behaviour and/or properties and view them as a segment on graphs such as event segmentation, funnel analysis, and retention analysis (207). That means that for example a custom definition of a group of users who only completed a certain number of modules or viewed a certain number of videos can be created. This further can be used to determine the usage threshold of users (to determine a group of users that represents the minimum usage threshold). In the event segmentation chart, the "Formula" tab in the bottom module of the chart control panel allows to write formulas to perform or calculate specific analyses and metrics on events (207).

Amplitude can track clicking on links, downloading documents and page close events only when data is sent to Amplitude. So, although Amplitude does not track these events by default a code was added on site and the configuration and the tracking of these events was enabled.

However, there is one feature that Amplitude still does not include and that is heatmaps. This is a feature that has been in discussion but it is still not available and this was confirmed via private conversation with the Amplitude support team (208).

Similar to the Matomo tracking method, Amplitude ensures that their platform is GDPR complaint (209).

5.4.3.20 Advantages of Amplitude

The Amplitude tracker is characterised with the following advantages:

- Friendly dashboard
- Additional features available

- Easy access to reports
- Data stored locally
- Track participants without influencing them
- Unlimited data storage
- Free to use
- GDPR complainant (configured automatically)

5.4.3.21 Disadvantages of Amplitude

The following disadvantages can be noted for Amplitude:

- Technical knowledge required for configuration and setup
- Technical knowledge required to extract data
- Technical knowledge required for implementing various features
- Technical knowledge required to uniquely identify users

5.4.4 Screen recorders

The ultimate mechanism for recording what a user has accessed and what content they have viewed is a screen recorder such as Wondershare filmora (210), OBS Studio (211), Apowersoft (212). There are also multiple options for mobile devices such as Screen Recorder by AppSmartz (213)(Android Play Store) and the inbuilt functionality on iOS. After trying several options, the Bandicam recorder (214) was used as most convenient.
These applications record all the interactions that take place as well as what content has been viewed.

5.4.4.1 Advantages of screen recorders

The advantages of screen recording software is self-evident, what the trial participant has done/viewed/interacted with is recorded, nothing is missed.

5.4.4.2 Disadvantages of screen recorders

There are several disadvantages to using screen recorders:

- Each recording needs to be watched and the "events" recorded manually.
- Trial participants would need to install screen recorders on each device they use to access a web-site.
- Trial participants must remember to record every time they use an intervention website.
- Trial participants would need to send the recordings to a research team.

5.4.5 Uniquely identifying users

Obtaining data from all participants can provide some insight into the usage of a web-based intervention but that does not suffice for a proper insight into how much a web-based intervention is utilised. The ability to track each user individually will give a clearer image of the usage and deeper insight of engagement of each trial participant separately. It can then provide more meaningful data about the linkage of the usage with behavior change. This was discussed throughout the interviews and meetings with the participants from the TRACK study and the focus group study.

"Group based data is not good enough for the sort of analysis that we want to do. For example, if you want to examine the association between usage and behaviour change, you really need to have individual level data. Group level data is not good enough.

P2, Interview

"I just want to- I know this is (name's) expertise, but the individual level of usage was vital to this project, and we needed to track it through a study ID. So, we needed to be able to see using a study ID what pages people were landing on."

P4, Interview

"*Yes, we were able to tell who's doing what and then see whether the actual usage is associated with behaviour change*."

P1, Focus group 4

This is a crucial point and very important for web-based interventions so each of the tracking methods was specifically configured to be able to track trial participants individually.

5.4.5.1 Uniquely identifying users with server logs

By default, server logs are not linked to a particular user. Data can be filtered by an IP address but that does not necessarily mean that each user will always visit the site from a same IP address. Also, many people can use the same IP address, for example homes have one IP address but multiple devices connected to the router.

For example, a request in the following format

GET /vimeo-video/ HTTP/1.1

indicates that the subpage titled "Vimeo Video" was accessed. If number of users have accessed the same subpage for a number of times then this request will show exactly the number of times it was accessed but without providing an information on who actually accessed the subpage.
Given the nature of these log files, it is possible to allow tracking of user access (once a user is logged in) by adding a parameter to the end of the URL to specify the user. In that manner a query string was attached to the URL in the following format

http://www.testusagemining.com/vimeo-video?UserID=999

to test manually whether the same URL will show in the server logs. Once it was confirmed a way of automatically adding of the query string for each user was implemented. To enable

this a new code was added on the site. Then a test was run to confirm that the requests are containing the User IDs. An example of such request after the code would be

GET /vimeo-video/?UserID=5 HTTP/1.1

that shows that User ID= 5 has accessed the Vimeo video subpage.
Two trialists shared their experience with uniquely identifying users with server logs.

"*Um, the log files are stored in this database that tracks every action made on the website. The log files are coded like, each participant has a participant code so we can link all the entries to one participant. And each account is connected to an email address. For example, resetting passwords and these things, and we had the email addresses of our participants, so through that we were able to link the participant ID in the log files to our participants and to connect them."*

P14, Interview

"So, we spent a lot more effort on individually engaging people, and we also did similar stuff like you guys did. We didn't use Google analytics we had access to the whole back end of the system so we used the server protocols, basically, and we just we had a script where we could extract information and kind of sorted into bins so we could have for certain content, we could see statistics, how long they've stayed on the pages, how often they clicked stuff like that. So, I think in terms of variables and output it's quite similar to what you did but we could track it on an individual basis. And so, we could assign an activity index to each person and that's what we ultimately used for analysis and we tried to link that and correlated with other variables."

P2, Focus group 4

5.4.5.2 Uniquely identifying users in Google Analytics/Universal Analytics

One of the improved features in Universal Analytics is the Client ID. This is a unique client number (ID) that is assigned to each user regardless of the number of times a user (client) visits the site (215). The downside of this feature is that Universal Analytics assigns different Client ID to the same user if a user accesses the site from different device or browser. For this reason, Universal Analytics introduced the User ID feature that has the capability to connect multiple devices, browsers, and sessions under same User ID (215). This helps to show users' usage activity across different platforms and devices and it was therefore very important to be implemented to uniquely identify users. Therefore, this was one of the main reasons for switching from GA to Universal Analytics for this research.

Instructions for setting up a User ID in Universal Analytics are given on their official website (216). The first step is enabling User ID in the Universal Analytics account and agreeing to the User ID policy. This configuration is simple and only takes a few minutes to complete. The second part of configuring the code to setup a User ID is recommended to be completed by a developer due to the complexity of the task. The code should be modified to generate unique IDs that will be assigned to users and to ensure that same IDs are reassigned to the returning users. Since this was a WordPress site enabling User ID possessed some challenges. One of the solutions that can be found online is using a plugin called MonsterInsights (217). This plugin allows for a very simple process of enabling User ID and only a few steps are needed to enable the feature. However, due to the cost of the plugin this was dismissed and the code was adjusted accordingly. The final step was to create a User ID reporting view.

Other trialists also confirmed the requirement for a developer to complete this process.

"Because it was quite confusing as to how to get the data for each participant."

P5, Interview

"Google doesn't actually want you to track individuals, like, we are doing. So, the programme needs to set up specific mechanics to make sure- they need to fool the Google system a bit to make sure that they can track individuals. Basically, one of our programmers has figured out how to get around them and obviously we used it."

P2, Interview

5.4.5.3 Uniquely identifying users in Open Web Analytics

Setting up User ID to enable uniquely identifying users in Open Web Analytics was difficult to execute and after a several attempts it was dismissed. Having code from other JS trackers at the same time potentially might have been a reason to prevent the code from working but after trying to overcome that and modifying the code still the User ID feature was not enabled. To try to solve the issue it was searched for solutions and options online as well as identifying a suitable plugin. However, this brought no results whatsoever. One challenge was the word 'Analytics' in Open Web Analytics which confuses the online results with Google Analytics and as for plugins no such plugin was found. The overall observation is that Open Web Analytics is lacking more responsive online support and this is a drawback of this tool. Due to this drawback the Open Web Analytics was not used in the advanced further testing of the tracking methods.

5.4.5.4 Uniquely identifying users in Matomo

The process of enabling User ID in Matomo was completed via WordPress plugin called WP-Matomo (218). The following options: WP User ID, Email Address, Username and Display Name (not recommended) were available to be shown as a User ID in the Matomo Dashboard. A username could have been chosen since data are sent on the webserver but if data were not sent on one's own server then the most sensible solution would have definitely be the WP User ID due to privacy concerns. For consistency with the other trackers it was opt for the User ID to uniquely identify users. This was tested quickly after enabling and it was confirmed that the User ID is enabled successfully.
Another trialist also shared his experience of using Matomo to uniquely identify users.

"I linked up to Google Analytics for broader kind of usage stats and then later on in the trial we rolled out with GP practices across the UK, and for that, because we wanted a bit of a fine a measure of metric cause precisely we were saying that Google Analytics what you can do is more individual tracking and find a bit of fluff with Google Analytics so I, we set up a Matomo as well to run alongside it along with a unique identifier that was linked up then to the data we were collecting, the behavioural data that we were collecting as part of the site. So, the intervention was kind of like hand washing and other infection control behaviours in the home, so there were sections where people could fill in kind of what they were doing and make a plan of what they were going to do. So, we generated a kind of a 16-digit randomised string but then was also linked up to the Matomo usage data, so we could track, combine the usage data there with the behavioural data."

P3, Focus group 4

5.4.5.5 Uniquely identifying users in Amplitude

As with other tracking methods, userid to uniquely identify users is not recorded by default in Amplitude. This tracker uses a unique sessionid (to uniquely identify a session) which, as discussed previously, is not sufficient to identify a specific user but allows all interactions in a session to be recorded and linked. In order to uniquely identify user (so that all sessions from a particular user are associated with that user), a similar process to that used for server logs and Matamo was employed. The userid was extracted using the WordPress API and associated with a specific variable that was sent to the Amplitude server. This code was written in JS by supervisor DA and implemented on each page in the test site.

5.4.6 Methodology for determining the accuracy of recording user interactions

The issues such as sampling in GA, incorrect setups, different tracking methods that measure differently website metrics, errors in JS code, or uniquely identifying users (for example the issue of uniquely identifying user when accessing from a different IP address or when deleting cookies) are known to lead to inaccurate data and potential discrepancies between data from

tracking methods (183, 219-222). Therefore, this project aimed to simulate data and test the accuracy of the tracking methods.

Two approaches were used to test the tracking methods:

- A Manual approach
- An Automated approach

The manual approach was used in the first instance to replicate the interactions of a single user, in order that the configuration of the different trackers can be validated, and the data recorded can be extracted and compared to that undertaken.

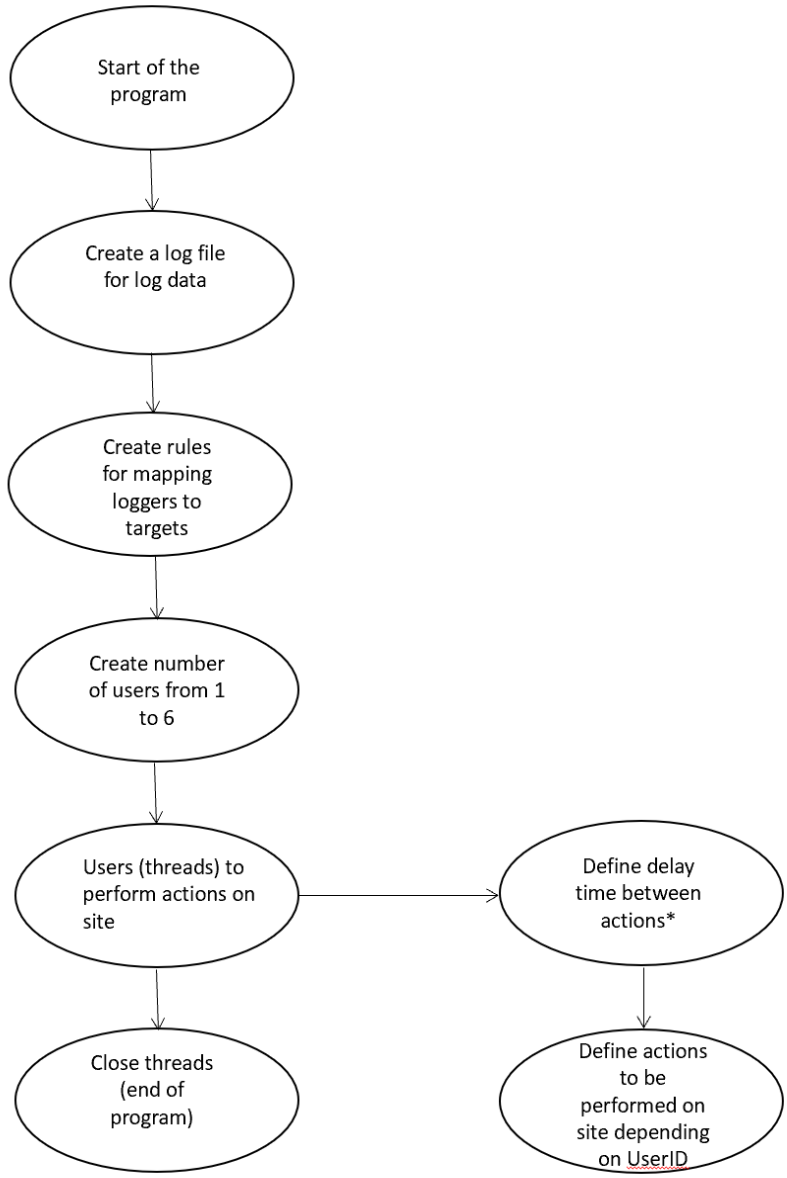
Once the configuration of the different methods was validated, an automated approach was used to replicate the use expected of the website in a real-world case, i.e. multiple user access at the same time. This approach allows for complex data-sets that can then be unpicked as described in section 5.4.7.3.

For the purpose of comparing uniquely identified participants predefined roles and users were created to assist with testing. These roles were created with different access privileges to the site so that could be assigned to users.

User interactions were tested on both desktop and mobile devices.

5.4.6.1 Development of the automated script

To emulate multiple user interaction at the sub-second level a simulation software in C# utilising the web browser automation software Selenium was written by my supervisor (DA). The flow chart below Figure 35 describes the simulation code.



* Delay time need to be setup otherwise the script will perform extremely quickly (milliseconds) which is not humanly possible and it would not serve its purpose to simulate 'real' users

Figure 35. Flowchart simulation code

5.4.7 Results: Accuracy of recording page views, timestamps, IP addresses and logins

At the beginning of the testing the accuracy of the following usage metrics was determined between methods: Page views (including Page Time Viewed), Timestamps and IP addresses. No additional configuration was required in the tracking methods. Later the accuracy of logins was also tested.

5.4.7.1 Interaction of a single user manually simulated for page views, timestamps and IP addresses

The interaction of a single user on the website on the desktop client was recorded using Bandicam and then the data from the different methods were extracted and compared against each other. Any time offsets were determined for each of the methods data stores.
Video recorded data were compared with server logs, Google Analytics and Universal Analytics data.
At this point the server logs were not setup to track individual user with a query string attached at the end and Universal Analytics was not enabled to track by User ID either. As this was at the very early stages the user was identified by the IP address for the server logs and with the Client ID feature in Universal Analytics. These drawbacks and configuration for the server logs and the Client ID in Universal Analytics were discussed earlier. For GA it was obvious that the view at the recorded time refers to the user that was manually simulated but the details were very scarce and this cannot be reliable way of identifying a user.
One example of the testing is given below (Table 27).

Table 27. Video recorded data compared with data from server logs, GA and UA– single user

Timestamp video recorded data	Timestamp server log	Timestamp Universal Analytics	Timestamp GA	GA activity on site	Website/Page Path video recorded data	Request server logs	Page URL Universal Analytics	Page View /Interaction
16:16:05	[15/Jul/2019:07:16:27 --0700]	16:16:00	16:00:00	/	www.testusagemining.com	GET/ HTTP/1.1	/	Accessing the homepage
16:16:10	[15/Jul/2019:07:16:33 --0700]	16:16:00	16:00:00	/youtube-video-2/	www.testusagemining.com /youtube-video-2	GET /youtube-video-2/ HTTP/1.1	/youtube-video	Opening the YouTube video subpage
16:16:13	[15/Jul/2019:07:16:36 --0700]	16:16:00	16:00:00	Not provided	www.testusagemining.com	GET/ HTTP/1.1	/	Opening the homepage
16:16:16	[15/Jul/2019:07:16:39 --0700]	16:16:00	16:00:00	/youtube-video/	www.testusagemining.com/ youtube-video	GET /youtube-video/ HTTP/1.1	/youtube-video-2	Opening the Hosted video subpage
16:16:53	[15/Jul/2019:07:17:16 --0700]	16:17:00	16:00:00	Not provided	www.testusagemining.com	GET/ HTTP/1.1	/	Opening the homepage

The IP address obtained from the web browser corresponded with the IP address from the server logs data and it was 77.28.163.68. The Client ID in Universal Analytics was 1816987088.15605.

The offset between the video recorded data and server log data was 8 hours, 59 minutes and 38 seconds and between the video recorded data and the Universal Analytics data 5 seconds. Based on the scarce details from GA the offset between the video recorded data and the GA data was 16 minutes and 5 seconds.

The manually simulated user accessed the homepage, viewed the YouTube video subpage, returned to the homepage, opened the Hosted video subpage and returned again to the homepage. The server logs showed the correct requests of accessing the homepage and the subpages in exact order. The details provided by Google Analytics were very scarce; they only showed 5 pageviews and 3 unique pageviews at approximate time of 4 pm which means that the exact time was not given. They also did not indicate sufficient details about the interactions on site and data cannot be filter by an IP address either. The Client ID feature in Universal Analytics helps identify the user and gave exact time of accessing the website so data did match. As stated earlier the Client ID does uniquely identifies a user but the issue arises when the user switches to another device, browser or deletes the cookies so this cannot be a reliable way of uniquely identifying user. IP addresses are not available in GA reports (223, 224).

The offset between the video recorded data and the tracking methods could be due to the difference in time on the server and the client, and as this was consistent and the relative time between interactions was correct, this was not thought to be of any concern. This applies to all trackers.

A second set of data was simulated manually to check video recorded data with data from Open Web Analytics. The initial testing was of a single user and one example is shown below (Table 28).

Table 28. Video recorded data compared with Open Web Analytics data – single user

IP address from web browser and Open Web Analytics	Timestamp video recorded data	Timestamp Open Web Analytics data	Webpage/Page Path video recorded data	Page view/Page title Open Web Analytics	Page Path Open Web Analytics	Page View/ Interaction	Visit length Video recorded data Open Web Analytics
46.217.156.117	19:31:47	10:32:56	www.testusagemining.com	Test Usage Mining	/	Accessing the homepage	00:00:33
	19:32:15	10:33:24	www.testusagemining.com/ youtube-video-2	YouTube Video - Test Usage Mining	/youtube-video-2	Opening the YouTube video subpage	
	19:32:20	10:33:29	www.testusagemining.com/ vimeo-video	Hosted Video -Test Usage Mining	/vimeo-video	Opening the Vimeo video subpage	

Offset between computer time and OWA time in WordPress was 8 hours, 58 minutes and 51 second.

The manually simulated user accessed the home page, then accessed the YouTube video subpage and the Vimeo video subpage. Video recorded data compared to the Open Web Analytics data matched exactly. The IP address, timestamps (including visit length and time between timestamps or actions on site) and page views (actions on site) were exact.

5.4.7.2 Interaction of multiple users manually simulated for page views, timestamps, IP addresses and logins

Interactions of multiple users were video recorded using Bandicam accessing pages in a random order. These interactions were performed manually and users were accessing the site in a sequential and in a non-sequential manner. Video recorded data were compared with Universal Analytics, Matomo and Amplitude data. At this stage the User ID was enabled for the three trackers. The Open Web Analytics was dismissed at this point due to previously explained issue with uniquely identified users in section 5.4.5.3.

The following example shows users accessing the site in a sequential manner (Table 29).

The following data were video recorded for Users with IDs = 5,4 and 3.

Table 29. Video recorded data compared with data from UA, Matomo and Amplitude- multiple users sequential manner

User ID	Timestamp video recorded data	Timestamp Universal Analytics	Timestamp Matomo	Timestamp Amplitude	Webpage/Page Path video recorded data	Page URL Universal Analytics Matomo Amplitude	Page view/ Page title Universal Analytics	Page view/Page title Matomo	Page View /Interaction
5	11:34:42	11:36:00	11:36:29	11:35:29	www.testusagemining.com	/	Viewed Test Usage Mining- Test Usage Mining	Test Usage Mining	Accessing the homepage
4	11:38:23	11:40:00	11:40:10	11:39:11	www.testusagemining.com	/	Viewed Page Not Found - Test Usage Mining	Page Not Found - Test Usage Mining	Invalid for this user
	11:38:28	11:40:00	11:40:15	11:39:15	www.testusagemining.com /youtube-video	/youtube-video	Viewed Hosted Video – Test Usage Mining	Hosted Video – Test Usage Mining	Opening the Hosted video subpage
3	11:42:09	11:43:00	11:43:55	11:42:56	www.testusagemining.com	/	Viewed Page Not Found - Test Usage Mining	Page Not Found - Test Usage Mining	Invalid for this user
	11:42:14	11:44:00	11:44:01	11:43:01	www.testusagemining.com /youtube-video-2	/youtube-video-2	Viewed YouTube Video – Test Usage Mining	YouTube Video – Test Usage Mining	Opening the YouTube video subpage

The offset between the video recorded data and the Universal Analytics data was 1 minute and 18 seconds, between the video recorded data and Matomo 1 minute and 47 seconds, and between video data and the Amplitude data was 47 seconds.

The raw data from Universal Analytics, Matomo and Amplitude show that tracking methods tracked the interactions correctly meaning that they have tracked the page views (accesses) to the homepage and the subpages accurately. All trackers show that the User ID=5 view the homepage ("/"), the User ID=4 the homepage and the Hosted video subpage (URL: www.testusagemining.com/youtube-video/ hence /youtube-video indicates access to the Hosted video subpage) and the User ID=3 viewed the homepage and the YouTube video subpage (URL: www.testusagemining.com/youtube-video-2/ hence youtube-video-2 indicates access to the YouTube video subpage). Universal Analytics and Matomo also show that users with ids 4 and 3 did not have permission to view the homepage which is due to permission access privileges assigned to these users. At this stage the raw data from Universal Analytics did not show timestamp with seconds only hours and minutes. To resolve this later in the research a new dimension was added in Google Tag Manager and linked to Universal Analytics so that the exact timestamp would have been obtained.

The example given below shows users accessing the site in a non-sequential manner (Table 30).

The following data were video recorded for Users with IDs = 5,4,3 and 7.

Table 30. Video recorded data compared with data from UA, Matomo and Amplitude – multiple users non-sequential manner

User ID	Timestamp video recorded data	Timestamp Universal Analytics	Timestamp Matomo	Timestamp Amplitude	Webpage/Page Path	Page URL Universal Analytics Matomo Amplitude	Page View/ Page Title Universal Analytics	Page View/ Page Title Matomo	Page View /Interaction
5	11:10:40	11:10:00	11:10:45	11:10:39	www.testusagemining.com	/	Viewed Test Usage Mining- Test Usage Mining	Test Usage Mining	Accessing the homepage
	11:11:08	11:11:00	11:11:14	11:11:08	www.testusagemining.com/ vimeo-video	/vimeo-video	Viewed Vimeo Video – Test Usage Mining	Vimeo Video – Test Usage Mining	Accessing the Vimeo video subpage
4	11:08:38	11:08:00	11:08:47	11:08:39	www.testusagemining.com	/	Viewed Page Not Found - Test Usage Mining	Page Not Found - Test Usage Mining	Invalid for this user
	11:08:44	11:08:00	11:08:51	11:08:45	www.testusagemining.com /youtube-video	/youtube-video	Viewed Hosted Video - Test Usage Mining	Hosted Video – Test Usage Mining	Opening the Hosted video subpage

	11:08:49	NA	NA	NA	www.testusagemining.com /youtube-video	NA	NA	NA	Opening the Hosted video and switching to another user
3	11:09:02	11:09:00	11:09:09	11:09:02	www.testusagemining.com	/	Viewed Page Not Found - Test Usage Mining	Page Not Found - Test Usage Mining	Invalid for this user*
	11:09:05	11:09:00	11:09:12	11:09:06	www.testusagemining.com/ vimeo-video /vimeo-video	/vimeo-video	Viewed Vimeo Video – Test Usage Mining	Vimeo Video – Test Usage Mining	Opening the Vimeo video subpage
	11:09:24	11:09:00	11:09:32	11:09:25	www.testusagemining.com/ vimeo-video	/vimeo-video	Viewed Vimeo Video – Test Usage Mining	Vimeo Video – Test Usage Mining	Opening the Vimeo video subpage
	11:09:32	NA	NA	NA	www.testusagemining.com/ vimeo-video	NA	NA	NA	Opening the Vimeo video and switching to another user
	11:09:54	NA	NA	NA	www.testusagemining.com/ vimeo-video	NA	NA	NA	Switching back to this user the video has already finished

7	11:09:47	11:09:00	11:09:54	11:09:47	www.testusagemining.com	/	Viewed Page Not Found - Test Usage Mining	Page Not Found - Test Usage Mining	Invalid for this user
	11:09:50	11:09:00	11:09:57	11:09:51	www.testusagemining.com/vimeo-video	/vimeo-video	Viewed Vimeo Video – Test Usage Mining	Vimeo Video – Test Usage Mining	Opening the Vimeo video subpage
	11:10:16	11:10:00	11:10:23	11:10:17	www.testusagemining.com/youtube-video-2	/youtube-video-2	Viewed YouTube Video – Test Usage Mining	YouTube Video – Test Usage Mining	Opening the YouTube video subpage

The offset between the video recorded data and the Universal Analytics data was 40 seconds, between the video recorded data and the Matomo data was 5 seconds, and between the video recorded data and the Amplitude data was 1 second.

The raw data from Universal Analytics, Matomo and Amplitude show that trackers tracked the interactions correctly meaning that they tracked the views to the homepage and the subpages accurately even when users accessed the website in a non-sequential manner. In addition, again Universal Analytics and Matomo also show that users with ids 4, 3 and 7 did not have permission to view the homepage which is due to permission access privileges assigned to these users.

5.4.7.3 Interaction of multiple concurrent users simulated via simulation software

The interactions of multiple concurrent users on the website were investigated using the simulation software. This script (described in section 5.4.6.1) was designed to simulate multiple concurrent users accessing the website was run in PowerShell. The simulation process lasted for a duration of around 6 minutes. The randomly picked users were the users with the IDs: 15, 26, 43, 48, 52 and 56. The comparison of data was made between the logs and the Universal Analytics Dashboard data, Universal Analytics raw data, server logs, Matomo raw data and Amplitude raw data. The example below shows the simulated data for user with ID=15 (Table 31).

Table 31. Log data compared with data from UA (raw and dashboard), Matomo and Amplitude - multiple concurrent users

User ID	Timestamp log data	Timestamp server log	Timestamp Universal Analytics raw data	Timestamp Universal Analytics dashboard data	Timestamp Matomo	Timestamp Amplitude	Page View/Page Path log data	Request server log	Page view/ Page Path Universal Analytics raw and dashboard data Matomo	Page view/ Page path Amplitude
15	10:52:42	02:53:21	10:53:23	10:53:00	10:53:28	10:52:38	www.testusagemining.com	GET /?UserID=15 HTTP/1.1	/?UserID=15	/
	10:52:56	02:53:37	10:53:39	10:53:00	10:53:44	10:52:54	www.testusagemining.com/youtube-video	GET /youtube-video/?UserID=15 HTTP/1.1	/youtube-video/?UserID=15	/youtube-video/
	10:53:43	02:54:20	10:54:22	10:54:00	10:54:32	10:53:42	www.testusagemining.com/youtube-video-2	GET /youtube-video-2/?UserID=15 HTTP/1.1	/youtube-video-2/?UserID=15	/youtube-video-2/
	10:54:21	02:55:04	10:55:06	10:55:00	10:55:10	10:54:20	www.testusagemining.com/vimeo-video	GET /vimeo-video/?User	/vimeo-video/?UserID=15	/vimeo-video/

								ID=15 HTTP/1.1		
	10:54:54	02:55:41	10:55:42	10:55:00	10:55:43	10:54:54	www.testusagemining.com/test-images	GET /test-images/?UserID=15 HTTP/1.1	/test-images/?UserID=15	/test-images/
	10:55:27	02:56:14	10:56:14	10:56:00	10:56:16	10:55:27	www.testusagemining.com	GET /?UserID=15 HTTP/1.1	/?UserID=15	/
	10:56:00	02:56:47	10:56:48	10:56:00	10:56:49	10:56:00	www.testusagemining.com/youtube-video=2	GET /youtube-video-2/?UserID=15 HTTP/1.1	/youtube-video-2/?UserID=15	/youtube-video-2/

The user id 15 viewed the homepage accessing the Hosted video subpage, then the YouTube video subpage, then Vimeo video subpage, the Test Images subpage, the homepage and lastly the YouTube video subpage.

The offset between the log data and the server log data was 7 hours, 59 minutes and 21 seconds, between the log data and the Universal Analytics raw data 41 seconds, between the log data and the Universal Analytics Dashboard data 18 seconds, between the log data and the Matomo data 46 seconds and between the log data and the Matomo data 56 seconds.

When we compare the data from logs with the data from the tracking methods we can conclude that all data matched between themselves. That means that each tracker recorded every interaction on site (each pageview to the homepage and the subpages) and that all actions on site (pageviews) have been sequential so the tracking methods show all interactions in the exact order. The same results were obtained for the remaining User IDs.

5.4.8 Results: Accuracy of recording clicks, documents downloads, external links

The following usage metrics tested between the methods were: clicks (including clicking on various links external and internal) and documents downloads. The subsections below describe the process of configuring the tracking of the clicks in server logs, Universal Analytics/Google Tag Manager, Matomo and Amplitude. Once those were enabled it was possible to track the external links added to the website and the pdf downloads.

5.4.8.1 Setup of tracking clicks in server logs

Once the process of adding query string on subpages to uniquely identify users was implemented for the URL of the homepage and subpages the next thing was to add a query string to the pdf downloads in a similar manner. Again, the idea was to embed the query string to the pdf download link. A new code written by my supervisor (DA) was then implemented on site which allowed to track which user has clicked on the pdf downloads.

An example of such request after adding the code is

GET /wp-content/uploads/2020/02/Download-PDF2-.pdf?UserID=4 HTTP/1.1

indicating that User ID= 4 had clicked on the Download-PDF2 document.

5.4.8.2 Setup of tracking clicks in Universal Analytics/Google Tag Manager

To enable the tracking of clicks the Google Tag Manager was used which enables both the tracking of the links and the pdf downloads. This was completed following the online user guide and web literature on this topic (225, 226). Setting up events of this kind in Google Tag Manager usually includes creating the right tag (first selecting the Universal Analytics from Tag Type), setting the Google Analytics Tracking ID, setting up the event with the right parameters and setting up triggers (225). Depending on the event created they were modified accordingly.

5.4.8.3 Setup of tracking links in Matomo

In Matomo the configuration of tracking external links and the pdf downloads was not necessary as the tracker has already had these events as built-in features. Matomo can track external clicks and the list of all external URL's clicked by users can be find in the Matomo (Piwik) report. The same applies for the tracking downloads, a feature that allows to see when a user has downloaded an image, a pdf document or other type of download. The list of all supported file extensions that can be tracked as downloads was available on their official website (227). A very quick test was made manually with one of the created users in WordPress. The manually simulated logged in user clicked on the external links and pdf downloads and then it was confirmed that this tracker had successfully tracked these events.

5.4.8.4 Setup of tracking links in Amplitude

To enable tracking of external links and pdf downloads, a code was developed for Amplitude and added on the website to enable sending these data to the tracker. The code was written in JS and was setup to call the function "wumAmpSendClickEvent" every time a user clicks on an <a> tag. The function wumAmpSendClickEvent was then sending json to Amplitude that had the format:

'pageTitle' => The url of the page from which the link (<a> tag) was accessed

'linkID' => The id attribute of the link, if this attribute is not set or does not exist the recorded value is a blank

'linkDestination' => The value of the "href" attribute in the <a> tag, if it is empty or not set it is left as empty.

These data were all being stored in Amplitude. With the configuration of this code it was enabled to track both the external links and the pdf downloads. Since this code was setup to call the function "wumAmpSendClickEvent" every time a user clicks on an <a> tag this immediately meant that all clicks on external links are tracked. The pdf document again is inside an <a> tag which allowed tracking on these documents too.

For example,

```
<a href="http://www.testusagemining.com/wp-
content/uploads/2020/02/fred.pdf">Download PDF</a>
```

shows that the pdf document again is inside an <a> tag which represents a link.

5.4.8.6 Results of simulation for usage metric: clicks, document downloads and external links

Interactions of a single user when clicking on a link was tested. These interactions were manual and a mobile device was used for them testing.

The following data were video recorded for User with ID = 4 (Table 32).

Table 32. Mobile data compared with data from server logs, UA, Matomo and Amplitude

User ID	Mobile Device	Timestamp mobile data	Timestamp server log	Timestamp Universal Analytics dashboard data	Timestamp Matomo	Timestamp Amplitude	Page Path mobile data	Request server log	Page view/ Page path Universal Analytics Dashboard Matomo Amplitude	Page View /Interaction
4	Samsung A21s	11:36:22	02:36:14	09:36:00	09:36:27	09:36:23	/	GET /?UserID=4 HTTP/1.1	/?UserID=4	Accessing the homepage
		11:36:22	02:36:28	09:36:00	09:36:35	09:36:32	/youtube-video	GET /youtube-video/?UserID=4 HTTP/1.1	/youtube-video/?UserID=4	Opening the Hosted video subpage
		11:36:29	02:36:36	09:36:00	09:36:38	09:36:39	/test-images/	GET /test-images/?UserID=4 HTTP/1.1	/test-images/?UserID=4	Opening the Test images sub page
		11:36:32	02:36:47	09:36:00	09:36:41	09:36:42	/wp-content/uploads/2020/02/fred.pdf?UserID=4	GET/wp-content/uploads/2020/02/fred.pdf?UserID=4/HTTP/1.1	/wp-content/uploads/2020/02/fred.pdf?UserID=4	Opening the Download PDF document

The offset between the mobile data and the server log data was 9 hours and 8 seconds, between the mobile data and the Universal Analytics Dashboard data 2 hours and 22 seconds, between the mobile data and the Matomo data was 1 hour, 59 minutes and 55 seconds and between the mobile data and the Amplitude data 1 hour, 59 minutes and 59 seconds.

The manually simulated user accessed the home page, opened the Hosted video subpage, the Test images subpage and on this subpage opened the “Download PDF” document. Data matches between all tracking methods which indicates that all methods were setup to track clicks and they can track when a user is opening various documents available on a web-based intervention.

A second simulation was performed to check for the external links and again checking for the document downloads. The simulation was on a desktop device (Table 33).

Table 33. Video recorded data compared with data from server logs, UA, Matomo and Amplitude

User ID	Timestamp video recorded data	Timestamp server log	Timestamp Universal Analytics	Timestamp Matomo	Timestamp Amplitude	Webpage/ Page Path video recorded data	Request server log	Page Path Universal Analytics Matomo	Page View/ Page Path Amplitude	Page View /Interaction
5	11:47:59	[04/Aug/2020: 02:47:52-- 0700]	09:48:00	09:48:02	09:48:00	www.testusage mining.com	GET /?UserID=5 HTTP/1.1	/?UserID=5	/	Accessing the homepage
	11:48:27	[04/Aug/2020: 02:48:24 --0700]	09:48:00	09:48:27	09:48:28	www.testusage mining.com/vimeo-video/	GET /vimeo-video/?UserID=5 HTTP/1.1	/vimeo-video/?UserID=5	/vimeo-video/	Opening the Vimeo video sub page
	11:48:33	[04/Aug/2020: 02:48:30 --0700]	09:48:00	09:48:33	09:48:34	www.testusage mining.com/test-images/	GET /test-images?UserID=5 HTTP/1.1	/test-images/?UserID=5	/test-images/	Opening the Test images sub page
	11:48:37	[04/Aug/2020: 02:48:37 –0700]	09:48:00	09:48:38	09:48:38	www.testusage mining.com/wp-content/uploads/2020/02/fred.pdf?UserID=5	GET /test-images/?UserID=5&ClickedOnLinkId=&ClickedOnLinkHref=http://www.testusage mining.com/wpcontent/uploads/2020/02/fred.pdf?UserID=5 HTTP/1.1	http://www.testusagemining.com/wpcontent/uploads/2020/02/fred.pdf?UserID=5	http://www.testusagemining.com/wp-content/uploads/2020/02/fred.pdf?UserID=5	Clicking the Download PDF document link

	11:48:43	[04/Aug/2020:02:48:42 –0700]	09:48:00	09:48:43	09:48:43	www.testusagemining.com/test-images/	GET /test-images/?UserID=5&ClickedOnLinkId=&ClickedOnLinkHref=http://www.google.com HTTP/1.1	http://www.google.com/	http://www.google.com/	Clicking the External Link 1 (accessing google.com)
	11:48:49	[04/Aug/2020:02:48:49 --0700]	09:48:00	09:48:49	09:48:49	www.testusagemining.com/wp-content/uploads/2020/02/Download-guidance-.pdf?UserID=5	GET /wp-content/uploads/2020/02/Download-guidance-.pdf?UserID=5 HTTP/1.1	http://www.testusagemining.com/wp-content/uploads/2020/02/Download-guidance-.pdf?UserID=5	http://www.testusagemining.com/wp-content/uploads/2020/02/Download-guidance-.pdf?UserID=5	Clicking the Guidance document link
	11:48:57	[04/Aug/2020:02:48:54 --0700]	09:48:00	09:48:57	09:48:54	/vimeo-video/	GET /vimeo-video?UserID=5 HTTP/1.1	/vimeo-video/?UserID=5	http://www.testusagemining.com/vimeo-video?UserID=5	Opening the Vimeo video sub page

The offset between the video data and the server log data was 9 hours and 7 seconds, between video data the Universal Analytics data 1 hour, 59 minutes and 59 seconds, between video data and the Matomo data 1 hour, 59 minutes and 57 seconds and between video data and the Amplitude data 1 hour, 59 minutes and 59 seconds.

The manually simulated user accessed the home page, then opened the Vimeo video subpage, opened the Test images subpage, clicked on the document titled “Download PDF”, clicked the external link 1 (google.com), clicked the second document titled “Guidance” and then opened the Vimeo video subpage. All tracking methods tracked both clicks the documents downloads and the external link accurately.

5.4.9 Summary of findings for tracking methods

The Table 34 below summarises the characteristics of the tracking methods, the main advantages and disadvantages presenting an overview of the findings from this project.

Explanations of terms used in the table:

- **Basic technical knowledge** refers to minimum knowledge of IT, coding and programming. The process can be relatively easy if this level of knowledge is acquired.
- **Medium technical knowledge** refers to advanced level of IT, coding and programming. That means that the process is more complex to execute and higher level of IT knowledge is required.
- **High technical knowledge** refers to high advanced experience of IT, coding and programming. The task can be difficult to perform and highly experienced developer is required.

Table 34. Summary table of main features for tracking methods

	Server Logs	**Google Analytics/ Universal Analytics**	**Open Web Analytics**	**Matomo**	**Amplitude**
Configuration level	Basic technical knowledge required	Medium technical knowledge required	Basic technical knowledge required	Basic technical knowledge required	Medium technical knowledge required
Uniquely Identifying Users	Not by default; users can be identified by an IP address which will not suffice. Medium technical knowledge required	Not by default; users can be identified via Client ID which will not suffice. High technical knowledge required	No (the research team could not configure however further research might show that is feasible)	Set by default but basic technical knowledge required to implement	High technical knowledge required
Data Extraction	Basic technical knowledge required	High technical knowledge required	High technical knowledge required	Basic technical knowledge required	Basic technical knowledge required
Storage Capabilities	Unlimited	Unlimited (data can also be stored for a limited time if opted)	Unlimited	Unlimited	Unlimited
GDPR or equivalent complaint	Yes, if configured	No	Yes, if configured	Yes, configured by the method by default	Yes, configured by the method by default
Free to use	Yes	Yes (free and non-free versions available)	Yes	Yes (free and non-free versions available)	Yes

5.5 Strengths and limitations of the tracking web usage project

To the best of the author's knowledge, an evaluation of tracking methods in context of web-based interventions has not been done previously. This project evaluated five tracking methods and these, as noted earlier, were chosen based on a series of Google web searches and mainly noted to be used by the trialists in the SR, interviews/surveys and focus groups. These five methods were ranked amongst top nine web analytics tools used by professionals in several online reviews (175, 176, 196, 197).

This is not an exhaustive list of available trackers but it is a representative sample. Evaluating further tracking methods (as the number of these methods is very high, hundreds or thousands) would not make sense as other solutions utilise essentially the same methods.

This project covered seven usage metrics that are commonly reported and used in trials (127, 130). This set of metrics is also a representative sample as the number of usage metrics is very high and a real web-based intervention often includes many components and metrics that can be tracked.

5.6 Discussion

Usage metrics can be gathered using tracking methods and the evaluation of these methods is beneficial for trialists to understand which tracking method is most suitable to gather insight into the usage of a web-based intervention. Automated tracking is most commonly used and these tracking methods provide detailed information of interactions and usage metrics (3, 228). Recently a paper has been published that evaluated Matomo in a context of a real-life web-based intervention but the techniques can be applied to evaluation of all web-based interventions in general (2). This paper suggests an increased interest in evaluation of the tracking methods and contributes to the research field of how usage and engagement should be measured. However, at the time of submitting this thesis the literature on this topic is extremely scarce.

Evaluation of the tracking methods eased implementation and configuration, data extraction, uniquely identifying users, storage capabilities, cost of methods and relevant features for tracking usage in such interventions.

The ease of implementation of the tracking methods differed per method, but all tracking methods required at least basic technical knowledge. Tracking methods such as GA and Amplitude needed

additional technical knowledge to be configured as the implementation was more complex. Although this is based on the experience of the author this also corresponds with findings from Chapter 4 where 92.3% of the trialists relied on someone else to implement their method (usually a developer or a webmaster, implying a technical personnel). A number of online tutorials can also be found for the use of GA and the implementation process explaining the technical details again implying certain technical knowledge is required (229-231). This level of complexity also applies to the extraction of data. The server logs, Matomo and Amplitude have one click download data direct option but technical knowledge of operating the back-end system is again required. In addition to that the server logs, as discussed earlier and in Chapter 4, can have hundreds of rows so interpretation and understanding of those data can sometimes present a challenge for the trialists, suggesting again technical knowledge is required (125). Hundreds of rows in server logs have led to developers writing libraries to parse server logs files such as the R Apache Log Processor (209). When extracting data from GA and Open Web Analytics a code needs to be written so programming knowledge is essential and therefore these tracking methods have a more complex way of extracting data in comparison to the other trackers evaluated (232-234). However, extracting data is fundamental so that usage data can be later used for analyses as well as being able to link interactions on the intervention website with each participant. Uniquely identifying trial participants provides deeper insight between usage and outcome. The complexity of enabling this again required technical knowledge, with Matomo being the only tracking method that simplifies this process (again noting that technical knowledge of operating the back-end system is needed).

All tracking methods have unlimited storage capabilities so data can be stored as long as required. It was possible to adjust the duration for which the data was available, and all tracking methods allow for deletion of data. However, uniquely identifying users, the collection and storage of the data needs to be done in accordance to current rules and regulations. The GDPR introduced in 2018 in the UK is applied in the Data Protection Act (DPA) 2018 and applies to health and social care research (167) to maintain this regulation. Accordingly, the GDPR and the DPA 2018 apply to web usage tracking; personal data and consent need to comply with those (168). The definition of identifiers includes cookies as personal data too and any usage of personal data needs to be explained in detail (168). Server logs track IP addresses which also count as personal data. Personal data includes emails, usernames and anything that can potentially identify participants. Server logs, Open Web Analytics, Matomo and Amplitude adhere to current standard with regards to GDPR regulations if configured and used properly. The exception of

these methods is the GA that currently sends data to the USA and therefore it is not GDPR complainant (195). In this project we collected usage data from simulated users only and therefore did not use any personal information. Data were retained while analysed and deleted after analyses. However, in a research environment data may need to be retained for a longer period and it is crucial to clearly define the purpose of collecting data, informing the participants accordingly and obtaining relevant consent (235).

All tracking methods evaluated in this project have the advantage of being free to use (though paid versions may be available for some of the methods if a specific advanced version is required). Trialists may have limited budget for research so having free tracking methods available to use can be beneficial for their research. This was also noted in the Chapter 4 when some trialists talked about the worry if existing free methods ceased to exist. Also, free to use tracking methods may still incur some costs as discussed in Chapter 4, so this should also be taken into consideration.

The accuracy of the methods was checked in this project testing the following usage metrics: page views, timestamps, IP addresses, logins, clicks, documents downloads and external links commonly used metrics in literature (127, 130) and noted by trialists in the other projects in this thesis. Simulations were run with a single user and multiple users and accessing the website in a sequential and non-sequential manner to allow for complexity. Testing included multiple devices, desktop and mobile clients again to test their accuracy using various devices. Our findings suggest that the tracking methods can provide reliable data to trialists. Previously, research found inaccuracies especially when sampled data were used. For example, prior research by O'Brien et al (38) demonstrated that 58% of activity on a website was unreported by GA. Other blogs also stated why there might be inaccurate data associated with this tracker (220). In one of our focus groups two trialists also made comments regarding the reliability of GA. However, now the tracking methods provide accurate data with online literature supporting this statement (52, 236).

Although this project is the first of its kind in terms of determining reliability of these methods in a context of a test web-based intervention, our findings suggests that they are reliable in tracking usage data.

6. Investigating measuring and encouraging usage of and engagement with web-based interventions: A focus group study

6.1 Introduction

Based on the interview and survey findings from the TRACK study we identified the need to further explore the trialists' views and opinions related to the participants' engagement with and usage of web-based interventions and trialists' perspectives on how to increase participants' interaction. This is an important topic considering the current debate of how to measure engagement with web-based interventions. Therefore, to gather trialists' opinions a focus group project was developed to explore this subject and to develop material and guidance for researchers.

6.2 Aims and objectives

The aim of the focus group study was to develop material and guidance on measuring and encouraging usage of and engagement with web-based interventions.

The objectives of this study were to review and explore, with input from the trialists:

1. information about determining engagement with web-based interventions
2. views and experience with participants' usage of and engagement with web-based interventions
3. effect of design and features of web-based interventions on usage and engagement
4. views and experience on how to encourage participants to engage with web-based interventions
5. suggestions and recommendations on how to deal with low participants' usage and engagement

6.3 Methodology

A focus group is a qualitative design technique used to gather in-depth information about a specific subject through group interaction (237). The group includes selected individuals to share their experiences, views and opinions on the topic to collect data (237, 238).

In contrast to interviews that are created through a dialogue between the participant and the researcher, focus groups include dialogue and interactions between multiple participants; therefore, they can provide different data and additional insight on a given topic (239). The topic on usage and engagement is a broad subject and trialists sharing their experiences with other colleagues simulates discussion and brings new ideas, hence for this project it was decided to use focus groups as a research method. Unlike the TRACK study interviews and surveys when trialists were asked questions about their tracking method in particular in order to explore individual experience of the method in detail, the focus group discussed broader subjects relating to their trials. Focus groups are suited for this type of research in order to exchange views in a group setting, have a dialogue on the topic and confirm or disagree on opinions. In line with the phenomenology and descriptive methodology approach explained in Chapter 4 (sections 4.3 and 4.4) the same approaches were applied for the focus group study. The topic of usage and especially the term "engagement" in such trials is very broad and even though the discussions were on participants' usage and engagement, trialists views and opinions again rely on their lived experience of using tracking methods. As discussed in Chapter 4, a reflexive approach was used.

6.3.1 Online versus face-to-face focus groups

The study involved focus group meetings with international trialists involved in RCTs. Due to the COVID-19 pandemic, as for the TRACK study, contact needed to be remote rather than in person. Advantages and disadvantages of online versus face-to-face setting mentioned in Chapter 4 applied for the focus group project too. Focus groups are much more difficult to facilitate online as there is no eye contact to direct questions at particular participants to help engage those who may not be contributing as much as others. Again, due to the limited number of experts in this field conducting focus groups online allowed inclusion of trialists that were not only UK based. The limitation of this was that agreeing on exact date and time was more challengeable because participants were coming from different time zones. The smaller group setting was more intimate and enabled participants discussing the topic to feel that they are equally involved.

6.3.2 Ethical approval

Ethical approval was granted by the University of Liverpool, Health and Life Sciences Research Ethics Committee (Human participants, tissues and databases) review number 7981 on the 04/03/2021.

6.3.3 Eligibility criteria

Members of trial teams were eligible to participate if they were aware of details of tracking web usage or of engagement in web-based interventions as part of a RCT. The only exclusion criterion when recruiting trial team members into this study was the inability to speak English.

6.3.4 Sample size

It has been suggested in the literature that the optimal number of participants in an online group is 3-6 (240) compared to a face-to-face where usually the number of participants is eight (241-243). So, it was aimed to recruit 3-6 participants in each focus group. In a smaller group the topic can be discussed in detail allowing each participant to equally be involved. Based on previously conducted similar studies

(105, 244, 245) and the specific focus of the study (which limits potential participants) we anticipated needing to conduct 2-4 focus groups to reach data saturation (246-248).

6.3.5 Recruitment and sampling

The recruitment process started with eligible studies identified in the TRACK study from Chapter 4. Interview and survey participants (n= 17) who provided consent to be contacted for any future related studies were contacted to participate in a focus group. Corresponding authors (n= 61) from eligible studies from the TRACK study who did not respond to previous invitations for the TRACK study were also sent an invite (Appendix 9) for the focus group study.

A primary search of PubMed was supplemented with searches of The Journal of Medical Internet Research, Google Scholar and Scopus to identify trials that had been published recently and not yet been indexed in PubMed as well to include preprints. The search strategy was identical as in *Table 16* in Chapter 4.

All trialists (n= 163) were contacted via invitation email (Appendix 9) and contact details of eligible team members were requested when appropriate. Each potential participant was invited to take part in a focus group meeting. A description of what the focus group would entail was included in the email invitation. Participants who had already participated in the TRACK study were sent one invitation email only. Other potential participants were sent a reminder email after the initial invitation email if they did not respond within two weeks.

The flow chart of the recruitment process Figure 36 is given below.

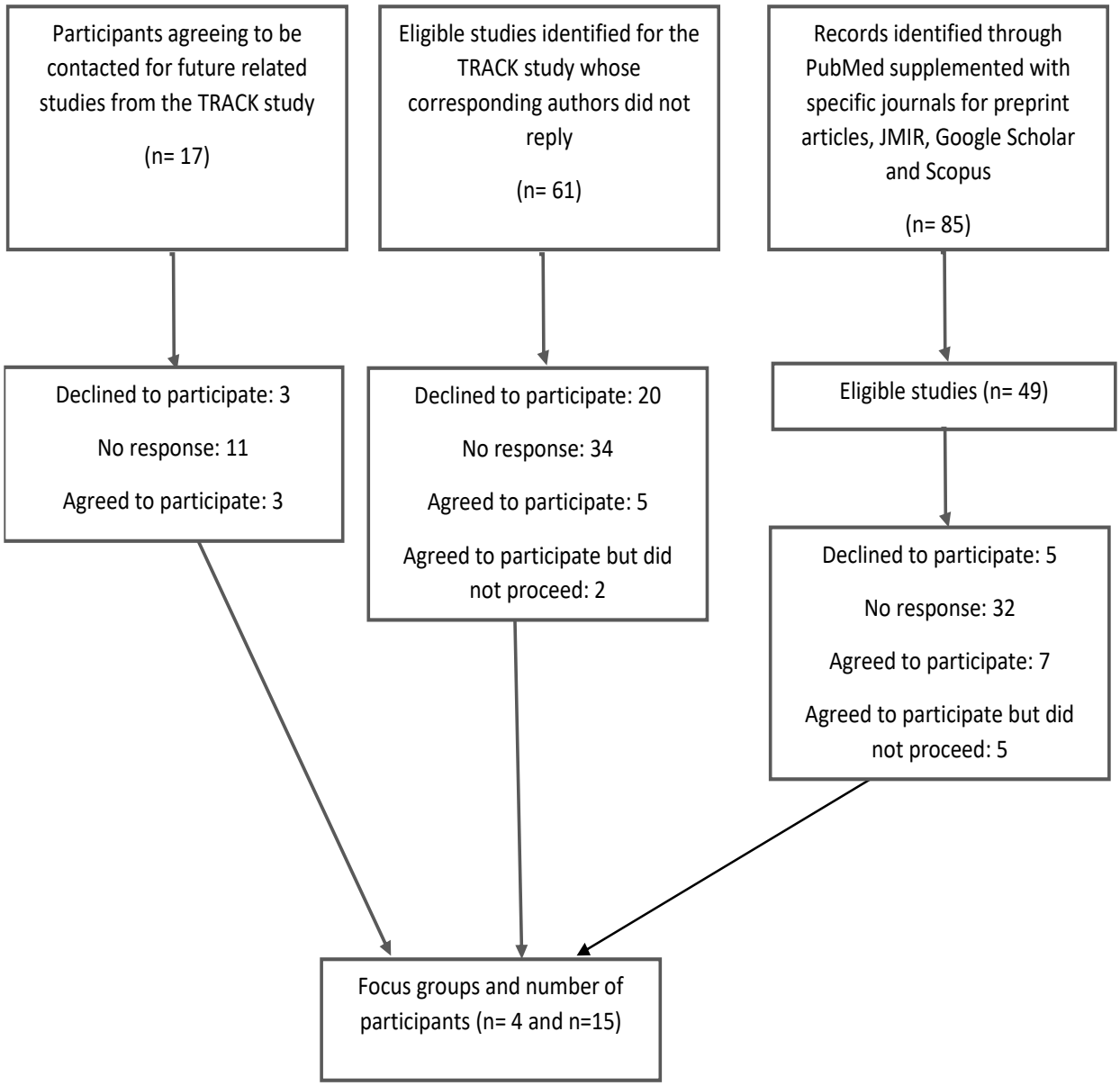


Figure 36. Recruitment process flow chart

6.4 Focus group meetings

6.4.1 Arranging focus group meetings

Once the corresponding authors responded to register interest in participation, a suitable date and time was arranged for the focus group meeting and a calendar invite was sent to the participants confirming the date, time, and the platform. Trialists were given the option to have the meeting via Zoom (100) or Microsoft TEAMS (101) platforms.

6.4.2 Informed consent

Prior to participating in the focus group meeting a signed consent form was required (Appendix 10). Once received the author also signed the form and emailed back to the participants a copy for their records.

At the beginning of the focus group, even though the written consent was obtained, participants were asked again to verbally consent to video recording and were reminded that they could leave the meeting at any point should they wish. After approval, the meeting commenced with the author explaining the aims of the study and providing an opportunity for questions.

6.4.3 Focus group conduct

Appendix 11 lists the focus group topic guide. This was developed based on the discussions by trialists on the topic of usage and engagement from the TRACK study. To the best of the author's knowledge no study has been done investigating the topic in exactly the same manner. The initial proposed topic guide by the author was reviewed and amended after discussion with the supervisors identifying main themes and questions to explore the topic in-depth.

When the focus group meeting commenced, it followed this guide which explored:

- how engagement was measured and all usage metrics used to determine engagement
- the effect of design and features that enhanced the usage and engagement
- most valuable lessons learned with regards to engagement including any challenges and preferences at the design stage

- suggestions and recommendations for encouraging usage and engagement and dealing with poor usage or engagement.

As for the TRACK study no incentives were provided to the focus group participants.

6.4.4 Data analysis

Meetings were video recorded, transcribed verbatim, checked and anonymised. NVivo Pro 12 software was used for organising and indexing data (106). As for the TRACK study, data were analysed using a thematic approach. The thematic analysis was conducted in the same six phases: gaining familiarity with the data; initially coding the data; developing the coding framework; defining and naming themes; completion of coding of transcripts; producing the results (Table 17). Data were coded independently by the author and all further queries on coding were directed to supervisors (SD, DA & KW) in cases of uncertainty. The focus again was modified to fit with the criterion of catalytic validity so that recommendations could inform future trial design (107, 108).

6.4.5 Confidentiality, data storage and consent withdrawal

Names, email addresses and (optionally) phone numbers were collected from participants who wanted to take part in a focus group meeting. These details were used to contact them to arrange meetings, send electronic copies of the consent form and study findings (if participants requested a copy). The contact details collected were not used for any other purpose and were stored separately from all other data.

The meeting video recordings were anonymised during the transcription process manually. Video recordings were deleted once the transcripts had been checked against the recordings for accuracy.

All data from the meetings were securely stored in an encrypted electronic file held on a University drive following data archiving procedures (to be stored for a duration of ten years). Publication of direct quotations from participants is necessary to report the results of the qualitative research, but no identifying information appeared in transcripts and therefore no such information appeared in quotations.

Consent forms were stored securely on the secure University drive separately so that no link between the transcripts and the meetings with the participants could be made. Consent forms were kept for checking purposes only.

Participation was entirely voluntary, and participants were able to withdraw at any time without giving a reason. Participants could choose to withdraw consent from all analysis (i.e. all data collected to be deleted) or to withdraw consent from further participation (but allow their data collected to date to be included in analysis). None of the participants withdrew from the study.

6.4.6 Risks and benefits

There was no foreseeable risk to participants and no undesired events occurred.

Eligible participants were able to select the time and date of the meeting conducted via web-based platform (e.g. Microsoft TEAMS or Zoom). All meetings were semi-structured yet conducted in a flexible manner to encourage narrative production and enable the author to change topic if needed. Participants were informed that they could leave the meeting, should they wish.

There was no expectation that study participants would benefit directly, although having the chance to express their opinion may have been useful, allowing them to air their views and to reflect on things. Taking part in this study gave study participants the chance to share their experience and views with fellow participating trialists who were also interested in tracking web usage and engagement.

6.5 Study results

A total of four focus groups were conducted involving 15 trialists. The first focus group had five participants, the second had three, the third four and the fourth three participants keeping in line with the estimated number of 3-5 participants in each group. At this stage it was felt that data saturation was reached as similar themes were identified and repeated across groups. The recruitment process started in March 2021 and ended in August 2021. All meetings were conducted via Zoom. Focus group meetings lasted from 60-80 minutes.

6.5.1 Demographic data

Data were collected on gender, country of residence, job role and area of research. Participants included seven females and eight males from nine countries, and the majority of attendees had an academic role such as professor or post doc researcher. See Table 35 below.

Table 35. Demographic table

Country of residence	**Number (percentage)**
Germany	3 (20%)
United Kingdom	3 (20%)
Australia	2 (13.3%)
Netherlands	2 (13.3%)
China	1 (6.7%)
Finland	1(6.7%)
Switzerland	1 (6.7%)
Ireland	1 (6.7%)
Japan	1 (6.7%)
Gender	
Male	8 (53.3%)
Female	7 (46.7%)
Job title	
Professor	5 (33.3%)
Post Doc Researcher	3 (20%)
Research Assistant	2 (13.3%)
Clinical Investigators	2 (13.3%)
Research Fellow	1 (6.7%)
Psychiatrist	1 (6.7%)
PhD student	1 (6.7%)
Area of research	
Psychology	5 (33.3%)
Medicine	3 (20%)
Health Science	2 (13.3%)
Physical Education	2 (13.3%)
Psychiatry	1 (6.7%)
Health Informatics	1 (6.7%)
Physiotherapy	1 (6.7%)

6.5.2 Engagement as a term

During the focus group meetings trialists discussed about the terms “engagement” and “usage”, including what the terms mean and how they differ, which was emphasised by the trialists in each focus group. Trialists opinions were that engagement is more than just the usage of the system and while usage can be measured by certain usage metrics, the same is not applicable for engagement. What a participant is actually thinking while using the intervention is not possible to gauge, bearing in mind that people are different in the way they react to the content and how they look at the intervention.

“*There's often a question what is really engagement? Because we often when we look at these web-based interventions quantify by clicks and pageviews and time on site but is that really engagement? What is really going on in the head of that person, are they really in that program, are they really interested or either just gone through the motions sort of and playing the game along. And so of course engagement is really in people's heads and not so much the number of clicks that they do but which is just suppose our best proxy for engagement is, I suppose, without going to people explicitly asking them questions about how much you were into that intervention*.”

P1, Focus group 4

“*At this time when I use the word “engagement” I talk about more than just the usage of the system. So, recently we published a scale, but also a paper on just the concept of an engagement and we see that as behaviour which might be related to actually usage of the system but might also be more the quality of how you use it, if it's a routine or things like that. Some people need to use the system, very often, for it to be effective for them. And a lot of people might not so if you see engagement as kind of also the involvement of an individual with system and something that's very much related to the effectiveness and it's a very individual measure which makes it's hard to just measure with like a wrong number that the more usage is better.”*

P4, Focus group 1

Comments were also given about the terms broader engagement, effective engagement and meaningful engagement. One trialist talked about their interest to look not just at the individual usage but to also map engagement among practices around the UK which allowed them to compare usage at different geographic places. Trialists discussed that the time spent engaging with the intervention does not always correspond with effective usage.

"And the other thing as well that is really interesting is because (name) who runs our department has developed the idea of an effective engagement. So, you know, not all usage is equal. Someone could be spending three hours on there but not have a change in behaviour because it might be that they're accessing things that they enjoy accessing but aren't actually making a difference to them. So, I think it is kind of evaluating, realizing that not all engagement is equal, because not all engagement leads to change in outcomes and so it's really highlighting that and it is not to say that people wanting to use the intervention and enjoying using it is unimportant, because if it gets people back then that is really important, but you also need to then get them to use the bits that are going to make a difference to support them."

P4, Focus group 3

"*What did you wish to had yeah, so I think that the problem with log data is that it's a lot of information and not all the information is meaningful. So, how do you make this information meaningful, because of course people can just click through a module, spent 10 seconds per page and have the module completed but really was that meaningful enough, like what was that you know enough to make what you are really expecting from that module to do."*

P5, Focus group 1

6.5.3 Metrics of engagement

Focus group discussions highlighted how trialists collect a combination of usage metrics and subjective metrics, as well as considering other metrics such as attrition, reminders and typing on the website, as shown in Figure 37. All metrics are described in the following subsections.

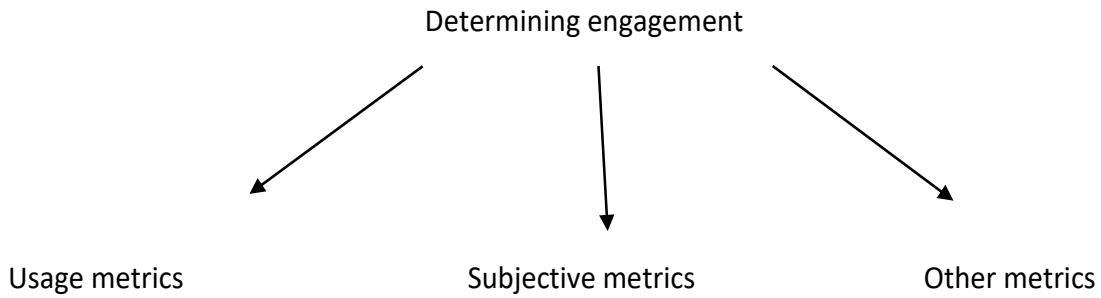


Figure 37. Determining engagement

6.5.3.1 Usage metrics

Usage metrics recorded and noted by trialists to determine usage were explored and these are shown in Table 36 with time spent on site and logins as most frequently used metrics. These findings are similar to the most commonly used metrics noted in the literature (127, 129, 130, 249) in the SR and the TRACK study. Pageviews were also frequently measured (including attrition across pages and number of pages viewed) and clicks (every click, how often they clicked parts on the intervention program, etc).

Table 36. Usage metrics recorded

Usage metrics	**Number (percentage)**
Time spent on site	10 (66.7%)
Logins	8 (53.3%)
Pageviews	6 (40%)
Clicks	4 (26.7%)
Timestamps	3(20%)
Video usage	2 (13.3%)
Web-based games	2 (13.3%)
Pathways	2 (13.3%)

Modules	1 (6.7%)
Sessions*	1 (6.7%)
Visits	1 (6.7%)
Documents downloads	1 (6.7%)
Others	8 (53.3%)

* The term “sessions” by the trialist was used to describe content components (similar to modules) and did not refer to the technical term.

Although trialists in the focus group study were not specifically asked questions about the tracking methods used, eight out of 15 trialists (53.3%) reported using server logs, three (20%) GA, two (13.3%) Matomo, two (13.3%) Life Guide software and one trialist (6.7%) reported using MonstersInsight plugin (217) (some trialists reporting more than one method).

6.5.3.2 Subjective metrics

Subjective metrics were described as being in the form of feedback and self-reporting data. Trialists relied heavily on subjective metrics, with 14/15 (93.4%) reporting using such metrics.

“We also had subjective data on how they experienced the parts of the intervention and how useful they found them and we also had lots of little interactive things in there, where they could enter some information or where they would be asked if they understood the content or if they had a question or how they rated it.”

P2, Focus group 4

The one participant who did not use subjective metrics for their trial described how they regretted not using them alongside their usage metrics. All participants agreed that subjective metrics are extremely important.

“In contrast to Dr (name) we quantitively measured engagement but solely with logins. So, we just measured how often, how many of the persons logged into our study platform which is on first view I

think a very nice measure to calculate how many persons logged into a platform, how often do they log into a platform, how the engagement develops over time, for example, during the during the study process. But I'm thinking about our study now, I think that it's not a measure which can give very deep inside, how this engagement process developed or how the participants experienced the platform or the study. And talking about qualitative possibilities to measure engagement, we did not have any insights how interesting the platform was, if there was some kind of enjoyment on the platform. So, we just have this one objective measure to say x percentage of the people logged in so often along this time."

P2, Focus group 1

6.5.3.3 Other metrics

Trialists discussed how other metrics used to calculate engagement were attrition, reminders and typing into the intervention website.

"Yeah that's a good point as well because that reminds me of another engagement metric which we haven't really spoken about is the non-usage attrition. So, at what points would people stop using it. So, it's sort of the derivative of other engagements like when was the last time they were on site, and when you look at your total group, how long are people going along and at what points people stop using it, is it halfway or at 75%, what's the survival rate. That is another way of looking at engagement as well, which I think is also very important."

P1, Focus group 4

Reminders were often mentioned by trialists and could have different forms. They could be generic non-personal reminders, for example sending participants a reminder that a new module is available, sending a weekly SMS to ask whether participants have completed exercises or reminding them about the benefits of using the web-based intervention.

"So, weekly reminders to remind participants if it's like a week you do one model per week. That we usually have been doing in our studies we are asking participants to do so, having email or SMS reminders or some other way of reminding them that hey the next model is now opening and you should continue with that. And also reminding them about the benefits as well, somehow at that point that this is what the content will be about."

P1, Focus group 2

Personal reminders were used when trialists knew exactly that there was little or no interaction or engagement with the system. When a participant is not using the web-based intervention as intended, reminders serve to encourage him or her to start or continue using it. For example, they may be sent when a participant has never logged in or if he or she stops using the web-based intervention. This type of reminder typically is more detailed regarding the engagement and usage of the participants than generic non-personalised reminders.

"Also, we use reminders and prompts as well, we use them in two ways if they didn't finish the session we would remind them to finish the session. But if they finished one and didn't start the new one, we had a different reminder so to start a new session. And they also came, I think we looked into some literature there what's the best period to remind them, it was, I think one or two weeks, indeed, after they lost contact so that was tailored based on when they last logged onto the program."

P2, Focus group 2

The final other metric mentioned by participants was typing into the intervention website, for example on a proforma or a discussion board.

"Last point, we also had a discussion board where they could ask questions freely and get like kind of like a virtual self-help group so we had lots of elements where they could really engage actively within the system."

P2, Focus group 4

6.5.4 Challenges and preferences when designing a web-based intervention

A challenge often mentioned by trialists was the analysis of these data. When data were collected, trialists described how they had a difficult job analysing data and deciding what to make of the data received. For example, they would have liked to have good algorithms to make valid conclusions or knowledge on how best to create new variables. Trialists were interested in exploring usage patterns to know which combination of usage metrics are predicting effectiveness.

"Okay, right regarding metrics and what I would have wanted to know it's about the complexities that (name) you just described it very well. I think it's easy like you said (name) to get all the data in but then you need a good algorithm to make valid information out of that and it's very hard to really from like click times or times how long somebody spends on a page to really extract information, how much information that this person really dedicate to that content. And I would really love to see more work on that specifically for certain contexts for different applications and ideally somebody would come up with the toolbox where you have prefabricated algorithms for certain scenarios, where you have like large scale studies like yours, or where you have interventions where you want people to engage with each other and stuff like that."

P2, Focus group 4

"I think one of the main issues we ran into is that collecting the data might not be the hardest part it's more about how you analyse and how you create all these new variables from. There are many things that I still would love to do in web-based interventions also looking for patterns, maybe in usage because maybe you can, like a combination of actions might be more predictive of effectiveness and then others

are just a raw numbers and that's something that maybe not that much related to collecting the data but more the analyse, the analysation stage which is something that I would very much look forward to do a little bit more."

P4, Focus group 1

Another challenge was associated with the accuracy of data. Trialists talked about the inconsistency of usage data between different tracking methods. They also compared the data with self-report data and these data indicated that participants did use the intervention contrary to the data obtained from the trackers.

"We sort of use, we captured the website analytics from Google Analytics and the monster insights plugin because that could kind of track across multiple devices, but it didn't always, it wasn't a 100% fool proof so sometimes for some reason he looks like the person hasn't actually engaged, but when you speak to them, they certainly have been. So, that yeah, I think that's not 100%. So, I suppose we also collected in the trial some self-reported measures which you know as rely on recall and so forth, but we sort of did that, as well, to make sure that we captured all of those who, for some reason, would not have been captured with the website data. I don't know if others have found that but that's what we found out with our way of doing it."

P3, Focus group 3

Figuring out which features would work was also an issue for trialists. Knowing exactly which features can engage participants more would have been very beneficial for them.

"I think there's a lot of unknowns whatever so this this... I mean in a lot of studies that we designed we kind of have to figure out what features work and what features don't work so that's kind of also figuring out are they going engage people or not and we don't yet know. For example, when we did the study with the social networking comparing that to a more traditional website without a social networking component is that oh we didn't know what is the evidence here, is that going to work or not. So, the

actual goal and purpose of the study is to find out more about how people will engage and what are the features that work and won't work."

P1, Focus group 4

In terms of preferences, trialists mainly talked about the correlation of usage with behaviour and understanding what metrics are available.

"*Yes, we were able to tell who's doing what and then see whether the actual usage is associated with behaviour change."*

P1, Focus group 4

"Maybe something more like if I knew more about how the, what are the best metrics in a sense, to evaluate the interventions in informative ways of what to develop, what to improve in them that's quite weird but that's, something that would be useful, would have been useful."

P1, Focus group 2

Other less frequently mentioned preferences were guidelines, increased granularity, measurements of long-term outcomes, questionnaires to measure engagement and determining usage of specific groups. Direct quotes on some of their comments are given in Table 37 below.

Table 37. Table of comments on less frequently mentioned preferences

Description	Comments
Guidelines (n= 1)	*"I'm less technical, so I can't really give you that web analytics but the way I thought to answer your question, what would have been helpful well if some guidelines were available at the time that would have been helpful."* P2, Focus group 3
Increased granularity (n=1)	*"I think what I know now and I didn't understand before is that it's also it would be super interesting to have metrics that like to describe the process of engagement over time because everything we did was calculated number. But like what really happens is, of course, someone like works a lot at the beginning and then not at all, maybe logged in again later, and all this is lost in our metrics and I still don't have perfect solution but maybe someone else has ideas on this. Um because I think, to really get an understanding we also need to look at the time spent on engagement, not on the numbers."* P2, Focus group 1
Measurements of long-term outcomes (n=1)	*"Also, this is something that I've been thinking about lately. Is that how to measure, how to assess the engagement outside using the actual lead program. So, what are the participants actually doing in their everyday life, are they applying the skills, the exercises learned in the program, are they actually doing it, so we can ask about it but how to ask about it that's the question."* P1, Focus group 2
Questionnaires to measure engagement (n=1)	*"I would say that I have been looking at various recent articles related to user experience metrics and subjective measures of actual engagement is there some kind of pseudo questionnaire short enough that we could use and good, suitable for our target audience as well. So, that's something if there would*

	be something like that that would be really great. Also comparable between different studies that would be great so I haven't used yet any such we have always been kind of making our own questionnaires or surveys." P1, Focus group 2
Determining usage of specific groups (n=2)	*"And regarding like background knowledge also, I think it would be very interesting to look at psychological variables that are correlated with certain behaviours or certain of these metrics like self-efficacy, for example, or even just a big five personality that would help like tailor your metrics to certain target groups and you might have certain patterns that you can identify when you check for these additional parameters in the users."* P2, Focus group 4

6.5.5 Effect of design features on usage and engagement

During the first focus group, two trialists stated that they were not able to recommend any specific features related to usage and engagement. This was said based on their experience with these trials, recognising that they cannot specifically state whether some features really influence the usage and engagement.

"We haven't, so in our studies, like the one I was describing, we didn't look into specific tools or specific content. We have done work with because we collaborate as well with Microsoft researchers of Cambridge and they are experts in artificial intelligence and all that and we tried to do some machine learning analysis applying to all the log data, and also all the different levels of granularity. And we haven't found anything that stands out, right so at that level I wouldn't, I think, at least from our perspective we haven't been able to identify specific features that are you know related to engagement."

P5, Focus group 1

"I think this is just a very, very difficult question. I think it depends a lot on what kind of intervention. I've done a few studies that really focus on whether or not certain features enhance adherence to an intervention and I haven't found anything. I've done a study on whether the design influence well engagement in a certain way, and that was more like involvement so that was a little bit earlier than our work on engagement now."

P4, Focus group 1

However, the majority of trialists shared what they found useful in their trials. Even the two trialists above who stated that they could not recommend any specific features, mentioned features or designs that they found useful.

"*Of course, there are features that we assume based on the previous literature that are related like, for example, the ones that we will are reminders, like the use of reminders is going to relate to higher use at least at the earlier stage*."

P5, Focus group 1

"But what we saw is that the design of an intervention, for example, game versus pretty plain influence how people view an intervention, how involved they are so precursor our parts of engagements. So, those kinds of things we can do, but at this moment my line of thinking is much more that we can use engagement, or at least the way people if human intervention as a way to select which features should be in there for these particular individuals. I would turn it around and say okay let's make different versions of an intervention, have people try them out, see where they score higher on engagement and say hey this is your perfect intervention. Because at this time, I think, on a general level, there are very little features that we know that will influence engagement, the same way for everyone that's just a very, very difficult question at this point. "

P4, Focus group 1

Other trialists talked extensively about the effect of design and features, and how they can increase usage and therefore potentially also increase engagement. The most frequently mentioned were the user experience (UX), testing and human involvement and personal contact, features that trialists thought can make the most impact. The list of all features and effective designs was extensive and these are summarised in Table 38.

Table 38. Effective designs and features to enhance usage and engagement

Recommended features and designs	**Number (percentage)**
User experience (UX)	12 (80%)
Testing	8 (53.3%)
Human involvement and personal contact	7 (46.7%)
Reminders	6 (40%)
Interactive content	5 (33.3%)
Target population	5 (33.3%)
Tailoring	5 (33.3%)
Gamification and rewards	4 (26.7%)
Bookmark system	2 (13.3%)
Goal setting and self-monitoring	2 (13.3%)
Multiple modes	2 (13.3%)
New information	2 (13.3%)
Participatory design	2 (13.3%)
Social networking	2 (13.3%)
Role model	2 (13.3%)
Website design	2 (13.3%)
Autonomy	1 (6.7%)
One URL	1 (6.7%)

The most frequently mentioned feature, UX, was mentioned by 12 (80%) trialists. Trialists talked about the need for the intervention to be easy to navigate, user-friendly and personally relevant for them.

"*And I suppose something that we haven't yet touched upon but which is also important, I think, for engagement is your website needs to be user friendly right? So, you can have all the right features on there that we know these are the evidence-based behaviour change sort of techniques that we implemented but then you can still have sort of crappy website that is conky, it's not easy to navigate*

and the phones are too big or too small, whatever it is, and the colours are ugly and so. If people hate the website even though it's useful they'll also stopped using it."

P1, Focus group 4

Testing was also mentioned as an important part of the development process when designing a web-based intervention. Sometimes minor details can be overlooked that impact the use of the intervention; also the way the intervention is planned and used can be different. Therefore, testing can help avoid these issues.

"*Do your own sort of testing because you may think you're on a gold mine but then maybe people don't like for whatever reason because there is a little detail, the X button is just not on the right spot it could be but yeah definitely do a pilot testing*."

P1, Focus group 4

Human involvement and personal contact were also valuable features mentioned by trialists. They described how personal contact can help reduce attrition and help participants remain engaged in the study.

"*For us a really important concern was keeping people committed and push through until the end. In most web-based interventions you have a huge dropout rate especially when you don't have this personal contact and we had a very, very low dropout rate almost everybody finished and we thought that really is a sign that they were committed and emotionally bound, and I think this is a good metric*."

P2, Focus group 4

Reminders were often mentioned in all the focus groups as a feature to help increase interaction with the web-based interventions. Regardless of whether they were personalised or non-personalised, participants may find reminders to be very useful.

"So, yeah intrinsic motivation, of course, the program itself the intervention itself has to be interesting, enjoyable useful but still having something to reminded them is very important."

P1, Focus group 2

Similarly, interactive content was highly rated as a feature to enhance participants' engagement. Avoiding just reading or listening but being active on the intervention to up the degree of interactivity in the program can bring more enjoyment to participants.

"Yeah, I think long gone are the days of static websites so just told you what to do and everything was going to be fine. Yeah, really need interactive designs that will engage the people, be fun. People need to have a reason to come back if there's no reason to come back they will definitely not come back. And so interactive features will give that sort of reason to come back and keep using the website and so definitely look at the evidence from previous trials and what they've found and try to implement that as best as possible."

P1, Focus group 4

Tailoring the design of the web-based intervention to participants' preferences was also mentioned, so that the information/content is relevant for participants.

"Um, one thing that we use which I think is tailoring and kind of personalisation I think that's one we try and do often to give people an element of choice in what they're viewing and then allow the information that they see further down the line to then be tailored to questions or choices they've made earlier in the intervention."

P3, Focus group 4

Opinions were divided on the gamification and rewards; some trialists thought that this would keep participants more involved while others felt that it may decrease the intrinsic motivation.

"Yeah, and with gamification there are other things as well, like you know, giving people rewards for reaching the certain amount of steps or points or whatever it is. So, people can give each other gifts or mountains or whatever it is so there's a range of little tricks and yeah, the evidence is quite supportive of gamification. People like that sort of stuff so, yeah, it works."

P1, Focus group 4

"This is super interesting. Again, from a psychologist side of view I just want to add like the gamification stuff and like adding these little rewards is kind of like, I'm a little bit unsure if it's really the optimal thing that we want because it's like an intrinsic reward and it kind of distracts from the actual content and it might even kill intrinsic motivation."

P2, Focus group 4

6.5.6 Lessons learnt

Trialists were asked to share their experience and thoughts on anything that they would have liked to know prior the study with regards to engagement. A common answer was that trial participants may not use the web-based intervention as intended; what people say and do can be different and participants may vary in how they use the web-based intervention Similarly, trialists who also used a person-based approach to develop their interventions stated that what people say in interviews does not always corresponds with what they actually do.

"I think, when you start such a trial, I think one of the things that you should keep in mind is that people won't use the system the way you think. And if you start with that conception it's much easier to think about okay, but how do I want them to use the system?"

P4, Focus group 1

"I recall a study, it wasn't a study that I was involved with myself but they were going to do a website, a physical activity website and before they've developed the website they went to do this whole formative research, talked to people what they wanted, how they want to use it, and you know, did focus groups and got a lot of information of it, built the website accordingly and then turned out people weren't using it, the way they've said they wanted it. So, there is really a valuable lesson in there, it's not because people think they want something they actually want it. I think, yeah, something to think about is what's the website used as intended, and so I think that's sort of goes as well, because you design something but people may use it in a different way than we anticipated or something is not used at all and something else is used pretty much more."

P1, Focus group 4

When talking about the most valuable lessons learned, the most frequent answer was the importance of informing and communicating with participants. Trialists felt that the "*journey of the user starts even before they start using the intervention"* (P5, Focus group 1) and therefore, communication is crucial. The way the intervention is explained to the participants is very important as well as how clinicians and investigators spread information and make contact.

"One of the other things we did halfway through the trial that I think is we are chatting up for another trial we were doing was people I think need to I don't think we were clear what they were going to get, and so I think we needed to be clear about the people's expectations, so that they will come in and know what they are going to get and not coming thinking oh I thought it was going to be this so I'm going to drop out. So, we thought when we're doing a screening and things to be a lot clearer to people about what it is, and then I think that helps if you like engagement, because it meets their expectations. So, you know the marketing, if you like, and being very clear about what people are going to gain from it and who is suitable for so that you don't. I think a lot of times people get on to these programs and then go oh that's not for me, I didn't know, I didn't realise or so that was another thing to make sure people were really informed, if you like."

P3, Focus group 3

Another important point was the value of the intervention from the participants' perspective. Participants need to feel that the intervention will bring value and that it is going to be useful for them.

"There must be something that is content wise is interesting or the social group must be somewhat rewarding or the gamification must be so much fun or there must be something that pulls you in emotionally and that pulls you over that level where you make a commitment and you say okay it's worth it, I make the investment, where I present myself or I will make a contribution because I feel indebted for all that great stuff I got."

P2, Focus group 4

Trialists also noted that fellow colleagues should be encouraged to report on usage metrics regardless of whether or not the intervention was found to be significantly effective or used much.

"One should be objective and transparent and, of course, try to publish these low usage data. I think that's quite important to fight a little bit against this publication bias because I think the insights into unsuccessful interventions are maybe, a little bit or maybe even more important than just publishing positive results in this context."

P2, Focus group 1

"Something that, as a researcher when I read other papers and they don't report on metrics, they have done a web-based study and there is no report on metrics I get a bit frustrated because it's so easy to set up, and it may well be that researchers didn't realise how easy it can be done and that's what they didn't do it, but yeah I think it's that sort of information."

P1, Focus group 4

6.5.7 Suggestions for low engagement with web-based interventions

When there is a low engagement with a web-based intervention, it can be very difficult for trialists to know exactly what to do and sometimes it may even be impossible to substantially improve engagement.

"That's a difficult one, if we had this answer we can all go."

P4, Focus group 1

"I think it's sort of tough question and what do you do when people aren't using the website? From a research point of view, when you find that out is probably too late because the money is spent and probably you don't have any other sort of money to go fix it and, but in the real world, and if money is not an issue, mostly it is I suppose is to go back and redesign and trial and error and until you finally do your tracking and make changes and see whether it improves or not."

P1, Focus group 4

Trialists agreed that the first thing to try to do is understand and investigate the reason for low engagement.

"*Well, the first thing it would be to try to understand why it is low."*

P3, Focus group 2

"Will try, yeah. I think, it's important to know why. So, just low usage might be a problem, of course, but it might also not so much be a problem, and so the individual engagement, are there reasons why people use the system or do not use the system, I think it's very important. So, first look back at okay, what is low, and is that people do not use certain features, or do not log in at all and try to look for causes."

P4, Focus group 1

When and why participants had stopped using the intervention can also indicate various reasons. When a high number of participants do not even start using the intervention something wrong or suboptimal in getting them to use even a technical issue or an update or a broken link may be a reason. When participants stopped using the intervention at certain point during the intervention then that might suggest content related issue or something may have overwhelmed participants. In order to gain understanding, trialists noted that it can be very useful to obtain feedback. Once the reason is established, trialists can try to resolve it accordingly.

"And I think when you're saying you know if you're having issues with engagement in your intervention, and I think it, for me it comes down to that too, so I think the quantitative data can be useful for looking outside in this is what we've had, if we've come across issues we first look at the quantitative data and see is there an element of the website where people are dropping out? Because that's then suggests that either there is a technical issue which we've had it once or twice where actually people have stopped using it because at a certain the point pages aren't working the way it's meant to work because you know, an update has happened or something's broken or it's something that's been missed. Or is there, you know navigation issues are parts of the site that people are finding or using so the quantitative data can be useful for that, but then also I think it's very important to look, to then do qualitative work which then will follow. "

P3, Focus group 4

Although there may not be a straightforward solution to the issue of low engagement and usage (as indicated in previous comments), some trialists still gave suggestions that may be useful to other researchers. These suggestions included the co-creation from the start, panel testing or improvements to the web-based intervention.

"I think the most important thing is co-creation, that you involve the target group from scratch, involve other stakeholders from scratch. For example, in my case, we made like a steering group before we started developing the intervention. We included type 2 diabetes patients and e-health experts, nutritional experts, someone from behaviour change, diabetes doctor and we got together every three

months to decide okay what's the best way, according to all perspectives to do with this program and I think the most important is your direct start group. Yeah, I think, involving all perspectives and co-creating are the most important things in my opinion. "

P2, Focus group 2

"I think that would be the way to deal with it, and maybe try to improve the intervention or the platform or the accessibility, if it can be improved in order to get high numbers."

P3, Focus group 2

Finally, trialists' opinions on what they think will make participants engage the most were associated with meeting and identifying participants' needs and their emotions or motivation. This is similar to the finding from Schubart et al (129) that adapting to participants' needs will lead to more engagement.

"And from our experience the people who would engage most and interaction really get committed to the program would be people who had a real demand and interest and where there was a psychological problem that was emotionally challenged to them, and you would meet their demand with our product basically. And so, to do that, we also had a screening so before we enrolled anybody in the study we would make sure that they had a certain level of psychological burden like anxiety or depression, and so there was already a certain ground demand for some support. And so, I think, maybe, if you could even go beyond that and having more specific diagnostics, for you like identify certain needs of participants and where can really then in congruent fashion time we meet this demand that should create a huge impact on reinforcing their commitment to the intervention, so I think diagnostic is another great tool here."

P2, Focus group 4

"One thing I thought was to ask the expectations, what the patient will get from this intervention. So, especially I see a lot of depressed patients and they have a lot of unsuccessful treatment before they come to our clinic so they think that this is one of another kind of a treatment, but maybe it's very important to ask what they think about, what they expect. So, those are very connected with the engagement and so like maybe depends on what kind of people or what kind of patient you intervene, but maybe those are things that should be asked initially."

P1, Focus group 1

6.5.8 Brief summary of key findings for usage and engagement with web-based interventions

The key findings from the study below are based on trialists' views, comments and opinions on the topic of participants' usage and engagement. These are summarised from trialists' experiences with web-based interventions with regards to determining engagement, increasing participants' usage and engagement, the importance of the patients' perspectives and the role of technology in web-based interventions. These key findings are used to generate recommendations for trialists because it was felt that it was important to be added in a pragmatic way for trialists to understand. The recommendations are summarised in Table 39.

6.5.8.1 Determining engagement

Based on the discussions on the term "engagement", it was evident that determining engagement is not straightforward. To determine engagement trialists from the focus groups suggested using usage metrics together with subjective metrics and others metrics. Usage metrics can include logins, time spent on site, modules completed, clicks, video usage, pathways, pageviews, and various others depending on the content of the web-based intervention. The subjective measures or qualitative and quantitative data can be in the form of a feedback, self-reporting data, or questionnaires. Other metrics that can be used include reminders, attrition and typing to the intervention website.

6.5.8.2 Increasing usage and engagement

To increase usage and engagement trialists suggested carefully designing the web-based intervention to include various features. Although as mentioned earlier it is hard to determine in advance which features would benefit participants, the majority of trialists still recommended an array of features and design suggestions based on their experience, listed in Table 38 including the UX as the top listed feature. Trialists suggested carrying out interviews of prospective participants to determine their views on what would increase their engagement.

6.5.8.3 The importance of participants' perspectives

The importance of participants' perspectives was agreed by all the trialists to play an important role. The main point is to make sure that participants' views are taken into consideration to enable meeting their requirements and expectations. Managing their expectations can help avoid drop out as sometimes patients may not fully understand what they will be getting with the intervention.

6.5.8.4 The role of technology in web-based interventions

The last key finding was associated with the blend of technology with the web-based interventions. Different populations may use the intervention differently, for example a younger population may access the intervention via their mobiles, whereas an older population may choose to use tablets or laptops. Participants typically have their own preferred mode of delivery; some will prefer to sit in front of a computer while others prefer to do things on the move.

Table 39. Proposed recommendations for the use of web-based interventions

1. Trialists to work with technical personnel at earlier stages of the design process to make sure current trends in technology are applied and applicable.
2. The functionality of the intervention needs to be tested with pilot testing by a panel from the target population.
3. The design of the web-based intervention should be interactive, user friendly, easy to use, easy to navigate, fit for purpose and tailored to participants' preferences.
4. Gamification and rewards to be considered carefully as they might work either way; they may increase the usage and engagement or diminish intrinsic motivation.
5. Interventions to involve a human and personal contact and provide immediate response to participants.
6. Interventions to include: new information to avoid generic and well-known information; a bookmark system to enable participants to continue where they have left; goal setting and self-monitoring features; and multiple modes as some participants may more learn easily via an auditory or visual mode.
7. Trialists to consider mobile apps as they are becoming increasingly popular.
8. Interventions should be accessible on different devices and compatible with older models.
9. In developing the intervention, trialists to consider inclusivity and the issue of technological literacy.
10. Privacy and security issues should be considered to ensure current privacy and security regulations are strictly followed.
11. More usage data should be collected, especially if data can be collected automatically without being intrusive to participants and carefully pre-select features and metrics.
12. Participants' views on the intervention should be gathered and in a variety of ways, including feedback, surveys, and questionnaires. It is important that participants' insights are obtained at all stages of the intervention.
13. To use reminders to maintain participants' interaction.
14. To explore patterns of usage to enable identification of popular features.
15. Patterns of usage to be linked with outcomes using an unbiased causal analysis to determine which are more beneficial.

6.6 Strengths and limitations of the focus group study

To the best of the author's knowledge this is the first study to investigate trialists' perspectives on participants' usage of and engagement with web-based interventions in this manner. As for the TRACK study, this study benefits from including trialists who were experts in this field based in the UK and internationally. Participation invites were sent to all newly published trials identified by the search. Again, due to the COVID-19 pandemic focus group meetings needed to be done remotely rather than in person which excludes having a direct, in person contact with participants which may have been more comfortable for them. Scheduling the focus groups was challenging due to participants being in different time zones. However, suitable dates and times convenient for all participants were agreed and the smaller group setting enabled all participants to be equally involved discussing the topic.

As for the SR and the TRACK study, this project did not search for RCTs that use mobile phone applications and social media.

6.7 Discussion

In the context of trials, participant engagement with web-based interventions is important to allow meaningful assessment of outcomes (228). The focus groups findings presented in this chapter suggested that a combination of various metrics (usage, subjective and other more general metrics) can be used to determine engagement. Our findings are similar to the proposed definition of engagement with digital change behaviour interventions by Perski, (228) that "engagement is the extent (e.g. amount, frequency, duration, depth) of usage and a subjective experience characterised by attention, interest and affect".

Combining these metrics is important to gather deeper insight about participants' interaction on the intervention website. Use of the intervention by participants does not necessary equate to engagement. As discussed earlier, participants may access the full intervention without engaging entirely or feeling that it has been beneficial for them; alternatively, a participant may find it very helpful accessing just one component of the intervention. Different participants may also require different "doses" (130) of the intervention to find it effective. Usage data are regularly used as the main source for measuring engagement but additional subjective metrics are also required (250). Subjective metrics are very

important as participants can share their views of the intervention, their satisfaction ratings, and evaluations of their experience. Usage data alone cannot provide this deeper insight.

Objective usage data are still extremely important, as they can provide valuable insights into the extent and patterns of usage of the intervention. Such data present valuable information to trialists, as they can see who is actually using the intervention and potentially detect a relationship between usage and outcomes (39, 130, 132). If participants do not use the intervention, then the content or design of the intervention cannot be associated with any outcomes. Usage metrics may not be reported either because trialists did not collect usage data or because they try to cover the fact that participants did not actually use the intervention much; however, trialists in the focus group suggested these data should be reported even when the intervention was not found to be significantly effective or used much. Other more general metrics that may be used (such as attrition, reminders, typing into the website) help to supplement objective and subjective metrics to get further information about participants' interaction with the intervention. Reminders for example can also facilitate usage and engagement as they can encourage and remind participants to complete the intervention.

Various features were mentioned by focus group participants as suggestions to help increase participant usage and engagement, including the user experience. Literature shows that enhancing the user experience leads to satisfaction with the program (251). Other suggested features include testing, and human involvement and personal contact which also corresponds with findings in the literature (129). Reminders, which may be generic or personalised, are also very useful to increase interaction, especially at earlier stages (252, 253).

Research suggests that interactive sections as part of web-based interventions positively influences patients' feelings of empowerment (254, 255). Therefore, in the design process interactive features should be considered and added to the intervention if possible. Having a tailored design has also been found to enhance levels of engagement in trials (249, 251, 256, 257) making the intervention more personalised to participants. Interactive content and tailored design should take into consideration the needs, abilities and technological experience of the target population.

Contrasting opinions were given on the topic of gamification and rewards between the participants in the focus groups. While some were in favour of these features, others believed that they can diminish intrinsic motivation and may distract participants from the actual content. However, game versus plainer

design can influence how participants view the intervention (35, 258) so it is a feature that should be carefully considered in the context of the trial and target population.

Focus groups proposed that the website design should be interactive rather than using more traditional designs that consist mainly of text, which is also supported by the literature (3, 259). This is similar to the finding reported by Danaher et al (260), who found that an enhanced website (tailored and interactive) attracted more participant visits and usage compared with a basic website (text based content).

Other desirable features to assist with usage and engagement include having a bookmark system; goal setting and self-monitoring features which represent key elements for monitoring symptom improvement (251, 261, 262); providing participants with new information, a feature also noted in this field to decrease attrition (129); incorporating participatory design; social networks to increase usage and engagement and meet participants' needs (also shown to be helpful in literature (129)); multiple modes; and use of a role model such as bot. Research on the use of chatbots and AI coaches to support guidance is becoming increasingly popular (245, 263, 264).

Trialists in these focus groups unanimously agreed that they have better results when they considered participants' views on the intervention. This recommendation is also provided in the literature (245, 262, 265) which highlights the importance of users' perspective in the development of interventions. Obtaining this insight is crucial as even seemingly minor technical issues, such as buttons placed in inappropriate places or an overly long video, can potentially irritate participants. It is important to consider participants' perspectives at all stages of the intervention design process.

The way the intervention is communicated to participants was also highlighted, and as one trialist stated "the journey of the user starts even before they start using the intervention". These findings suggest that good instructions and a clear format can encourage participants usage.

As technology and online treatments evolve, trialists are advised to keep up to date with technology, to avoid their interventions becoming obsolete (251). This may also help to improve the ease of using the intervention (39) (for example, if new advances help to make the intervention more user friendly) or allow designers to implement improvements to the design or features of the intervention. Trialists should aim for a design that can be used on multiple devices, small screens, with responsive designs and if possible dedicated apps to allow more options for participants. Different populations may use the technology differently, and therefore the intervention should be available to all in the target population

and compatible with various models. Although Vandelanotte et al, (257) found that a delivery mode preference does not influence the effectiveness of the intervention, allowing participants to use their preferred device can increase participants' satisfaction levels with the intervention and increase the user experience.

When designing the intervention trialists are advised to take inclusivity into consideration, making sure all participants have equal chances to use the intervention and participants that do not have technical knowledge are not excluded.

Health information obtained from participants in clinical trials need to follow regulations about privacy and security. Participants' data need to be protected and used legally, as discussed by trialists in the focus groups. GDPR applies to the European Union countries but other countries may have their own legal data regulations.

7.Discussion

7.1 Summary and interpretation of key findings

7.1.1 Current practise among web-based interventions in terms of collecting, reporting and analysing web usage data

This thesis began with a systematic review to determine the extent of web-based intervention use in RCTs and to ascertain current practice in terms of collecting, reporting and analysis of web usage data in such trials. The review demonstrated that the use of web-based interventions in RCTs has been on the increase over the last 15 years but the number is still low in comparison to the overall number of published trials.

A random sample of 100 trials involving web-based interventions suggests that such interventions are most commonly used for health promotion (42%) or mental health (32%). 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.

The collection of usage data is important to determine the extent to which the intervention is being used by trial participants and to link the effectiveness of the web-based intervention with the actual usage of the intervention. Knowing how and to what extent a user uses and utilise a web-based intervention can eventually provide valuable information not only on how much the web-based intervention was used but also to assist in estimating the efficacy of the intervention. Unlike subjective data which can includes various forms of feedback, these data are objective and can be obtained automatically without being intrusive to patients. Still, consent cookies are required and regulations for privacy and security of data need to be followed.

7.1.2 Tracking methods used to collect usage data

The majority of the 100 studies reviewed (90%) in the SR reported the collection of web usage, but over 50% of these studies did not mention the method used to ascertain trial participants' web usage. The most commonly reported methods were logs (predominantly server logs), website tracking data, GA and self-report data. The TRACK project, involving interviews and an online survey, was conducted to gather in depth information about trialists' use and experience of tracking methods. Findings from the TRACK

study show that the trialists involved mainly used GA, website platform feature, bespoke software and server logs to collect web usage information. In the subsequent focus group study, some trialists mentioned the tracking methods they have used. Those trialists mainly reported using server logs, GA, Matomo, and Life Guide software.

Overall, the findings from the SR, interviews, surveys and focus groups suggest that trialists most commonly use server logs and GA to collect web usage information, so these two methods were included in the tracking web usage project, which was conducted to evaluate some of the most popular tracking methods. Matomo was also stated to be used by trialists in the focus group study. Other tracking methods evaluated in the tracking web usage project were Open Web Analytics and Amplitude.

These findings suggest that trialists often chose a tracking method that is well-known, with some trialists opting for a bespoke software due to the specific requirements of the method in terms of their interventions. Trialists in the TRACK study described website platform features, and the studies included in the SR referred to website tracking data; but these references were vague, as these trialists were not involved in the technical implementation of tracking web usage. This suggests that the percentage of "known" methods in our results exaggerate the true percentage, if the exact method was not stated by those trialists.

7.1.3 Tracking methods implemented and used in context of web-based interventions

The tracking web usage project in Chapter 5 and the TRACK study in Chapter 4 both aimed to gather deeper insight into the use of tracking methods in the context of web-based interventions, with the tracking web usage project aiming at the technical understanding and evaluation of methods and the TRACK study using qualitative and quantitative data to combine the findings. Our findings indicate that technical knowledge is required to implement and configure the tracking methods. In the TRACK study, the majority of trialists (92.3%) relied on someone else to implement their method (a developer or a webmaster, implying technical personnel) which aligns with the tracking web usage project suggesting that certain technical knowledge is needed based on the author's experience. The level of complexity varies according to the specific software and task being performed; therefore, different levels of technical knowledge may be required, depending on the software/task.

Findings from the TRACK study suggest that mostly trialists would use their methods again, suggesting that use of a tracking method is helpful for trialists to gather insight about participants' behaviour on the intervention website. The advantages of using the methods stated by trialists were numerous, including the level of usage data provided, automated tracking, ability to track participants without influencing them, having a friendly UI, gaining objective metrics and being free or easy to use. Disadvantages again depended on the specific method used including being reliant on program developer, lacking good UI, limitations in tracking usage metrics, difficulties with extracting data, understanding the data or data format (majority of trialists in our studies noted difficulties with dealing data from the server logs as these logs can contain hundreds of lines).

The use of tracking methods in web-based interventions is highly important in order to provide objective usage data (3, 132). The accuracy of tracking methods for collection web usage data was rarely explored in the 100 sampled studies in the systematic review with only 4 (4.4%) of ninety RCTs reporting about reliability (86). In the TRACK study this was discussed with ten trialists and seven of those did check on the accuracy of their methods by conducting a testing phase. In one of the focus groups, trialists discussed sometimes having discrepancies between usage data obtained from the tracking method and self-reported data suggesting errors in the data from their methods. Having a testing phase to check the accuracy is important although findings from the studies suggest that trialists do not necessarily conduct a testing phase and simply assume that the method will be accurate. The tracking web usage project aimed to evaluate the reliability and accuracy of the tracking methods to investigate this issue. Findings from this project suggest that tracking methods can provide reliable data to trialists supporting current online literature on this topic (52, 236) and can be successfully implemented in health research (2, 3, 110). Some discrepancies noted by trialists might also be due to using previous versions of the tracking methods as tracking methods are constantly evolving and progressing. Certain tracking methods in the past had issues potentially influencing complete accuracy, for example the sampling of data in GA which now can be avoided in GA version 4 (219, 266).

7.1.4 Usage metrics used

Findings from the 100 studies sampled from the systematic review show that trialists collect and report web usage data using a wide variety of metrics, most commonly number of logins, number of individual intervention components (modules, sessions) and time spent on site. The TRACK study had similar findings, and in the focus group study, time spent on site, logins and pageviews were most commonly reported. These findings correspond with the most commonly metrics reported in literature (127-129). The tracking web usage project evaluated seven metrics: logins, timestamps (used to determine time spent on site), pageviews, IP addresses, clicks, documents downloads and external links. The decision to include these metrics was to gain deeper insight about the reliability of the methods and to allow for more complex testing. A combination of more than one usage metric is usually measured to provide a comprehensive picture on users' interactions of an intervention website, as such websites usually consist of numerous elements that can be tracked. This not only allows investigation into the relationship between various metrics but also gives insight on which components of the intervention are mainly used and which could be enhanced or improved. The techniques used to evaluate the usage metrics in the tracking web usage project could also be applied to other usage metrics.

7.1.5 Encouraging usage and engagement with web-based interventions

Intervention usage data are important to demonstrate whether or not the intervention itself is beneficial, i.e. when evaluating the intervention as part of a causal analysis, rather than just assessing the effectiveness of the treatment policy using ITT analysis.

If trialists have been able to collect usage data and have demonstrated that usage impacts positively on outcome, then it is important to encourage usage/engagement for future users to maximise effectiveness of the intervention. Usage metrics should be reported, regardless of whether the intervention was found to be effective or was used much by trial participants (132).

However, encouraging usage as part of a trial is also important, because if no-one uses the intervention in the trial, then it will not be possible to assess the impact of usage on outcomes.

It might be difficult to give specific guidance to all trialists about increasing usage and engagement given that the clinical issues/settings/needs of participants will vary according to the specific scenario.

However, the focus groups participants provided their views on the matter, from which general recommendations on this topic were created.

Several main features of the development and characteristics of the web-based interventions were noted to impact usage and engagement, with user experience being the most highly ranked feature. Other important features included testing, human involvement, reminders, interactive content, targeting the population, tailoring, gamifications and rewards with other features mentioned more scarcely. Human involvement referred to involving a professional (usually) to have a personal contact with the participants. Targeting the population was suggested to ensure that the intervention appeals to the relevant age groups, with features and design of the intervention adjusted according to the characteristics of the target population. The intervention design should be tailored to participants' preferences to include information and content relevant for participants. The general consensus was that web-based interventions need to be user friendly, easy to use and navigate, fit for purpose and personally relevant.

The next crucial point was the importance of the participants' perspectives which trialists agreed plays a massive role. All trialists agreed that is highly important to know participants' experience and views of the intervention and whether the intervention influenced their behaviour. The main point noted was to make sure that participants' views are taken into consideration to enable meeting their requirements and expectations. This enhances the value of qualitative data such as obtaining feedback from participants and supports findings in literature to adopt a person-centred approach (267).

The final point of importance to focus group participants was the blend of technology with web-based interventions. As web-based interventions are designed to be used via the Internet, on new devices and to incorporate newly technological features, the role of technology is extremely significant for such interventions and rapid technology changes impact hugely on such interventions (268). These interventions need to evolve constantly in order to be used as commonly used devices and Operating Systems develop continuously and upgrades are frequently introduced (268). Therefore, trialists agreed that it is advisable to consider current trends in technology to prevent the intervention becoming obsolete and to keep openness in their design to incorporate changes if needed or if some apps used become obsolete. Trialists should work with technical personnel to clearly understand what can feasibly be implemented. Trialists also suggested that the intervention should be easily accessible and compatible with different devices.

A few important points relating to technology were noted for careful consideration by trialists when developing their interventions. Inclusivity was one issue, as the more modern the technology the more people who do not use that technology may not engage, due to a lack of technological or computer literacy. Although the intervention may consist of important design features, if the study population is unaware on how to use them then they are not going to be used as intended or may not even be used at all. Studies suggests that higher levels of eHealth literacy can be positively related with good health lifestyle behaviour (269, 270). Therefore, the importance of communication and easy instructions for users is crucial as well as the importance of a logical well-designed format. Inclusivity also relates to the socioeconomic impact i.e. less wealthy people may not have access to the required devices. A recent meta-analysis study found that digital interventions (web-based interventions including mobile apps interventions and wearables) targeting psychical activity are not equally effective for people of low and high socioeconomic status (271). This finding strengthens the argument that these interventions are more effective for wealthier people with higher education. Additionally, if people with low socioeconomic status use the Internet less for health purposes and have lower computer literacy, this could influence their usage and engagement with the intervention.

The issue of privacy was also discussed by the trialists. The users of web-based interventions must be aware of the usage information that is collected from them given the introduction of GDPR. Therefore, the collection of health information from participants in clinical trials needs to follow regulations about privacy and security. Whilst GDPR applies to the UK and the countries from the European Union, other countries may have own legal data regulations that needs to be followed.

7.2 Concluding remarks

This project sought to guide trialists on best practice of collection and use of web-based intervention usage data to ensure consistent and reliable comparisons to be evaluated across studies. Usage data are necessary to determine the extent of intervention usage of trial participants and to link the effectiveness of the web intervention with the actual usage of the intervention. Usage data are most objectively obtained through the use of tracking methods, and these were explored in depth using qualitative mixed methods research and via a tracking web usage project. Our findings suggest that the use of these methods is important for trialists and that methods can be successfully implemented in the context of

web-based interventions providing reliable data to trialists. The concept of evaluating usage metrics and the tracking methods can be relevant for other metrics and other tracking methods. This form of evaluation is becoming more popular in this field as the number of the web-based interventions is on the increase. Combining usage data with other metrics and qualitative data leads to more detailed insight and evaluation of web-based interventions and outcomes. Focus groups were conducted to explore trialists' views on how to encourage participants' usage and engagement with web-based interventions. The findings from all elements of the thesis were used to develop recommendations for researchers when evaluating web-based interventions. Trialists are encouraged to focus on the needs of the participants, their perspectives and potential barriers that may face participants when using a web-based information. Web-based interventions can be designed to incorporate various features and designs to enhance interaction and enhance the user experience, including interactive features, human involvement, reminders and tailoring. Emerging technology should also be considered, considering the target population, current regulations, and computer and technology literacy.

7.3 Impact of this PhD

Negative effects on public mental health have been observed because of the pandemic COVID-19, with people needing to adhere to physical distancing, self-isolation, quarantines, and restrictions on socialising (272). Therefore, there is an increased need for remote interventions, as these interventions are promising to deliver health care and reduce the negative impact of the pandemic.

A review of SRs demonstrated that there were no previously published reviews of all web-based intervention studies, providing evidence of the novelty and usefulness of the present SR study. This study included web-based interventions in all health areas exploring the tracking methods and usage metrics used. Information was gathered on study characteristics, whether trialists checked on the reliability of their methods, prescribed "online dose", included CONSORT flow diagram and CONSORT-EHEALTH checklist, what instructions were given to participants on how to use the interventions, whether they reported attrition rates, as well as whether specific adjustment was made for intervention usage for any outcomes in the analysis.

The mixed methods study and the focus group study helped to provide an overview of tracking methods that are well-known and used in such interventions. The tracking web usage project then evaluated the

commonly reported methods identified within these studies in more depth, along with two additional methods. Evaluation of the tracking methods for these interventions have not (to the best of the author's knowledge) been done previously in this field for these purposes. Furthermore, the addition of methods not identified by trialists enhances the usefulness of this research, by including methods that may not typically be considered by trialists. Recently, a paper evaluated one of these additional methods, Matomo (2) in the context of a web-based intervention which suggests that the topic is gaining more importance. Although other tracking methods exist, evaluating more would not make sense as other methods utilise essentially the same methods. Trialists in the TRACK project often mentioned their interest in learning more about the tracking methods available and asked to be sent a summary of findings from the tracking web usage project. This demonstrated that trialists may benefit from such evaluation and therefore these findings will contribute to this field of research.

This thesis also explored the usage metrics in such interventions and with the tracking web usage project a variety of commonly used metrics were included in the testing phase of the reliability of the methods. Investigating the usage metrics helps to gain more understanding about participants' interaction with the intervention. Investigating the metrics also contributes to this field bringing more insight into this topic.

Recommendations from trialists on the topic of usage and engagement with web-based interventions were gathered by the focus group project to serve as guidance to other trialists when developing web-based interventions. This investigation into usage and engagement with web-based interventions across a variety of health areas in focus groups has not been done previously, to the best of author's knowledge.

7.4 Future work

This thesis did not include mobile phone applications or social media interventions. This was a conscious decision because the primary aim was to determine the frequency with which trialists monitored web usage. Future work could include assessing these interventions.

Changes can be suggested to the current CONSORT-EHEALTH checklist version 1.6.1 based on the findings from the studies. In addition to the usage metrics reported it can be suggested that trialists also include the tracking method used for obtaining usage data and report whether a testing phase was

completed to check on accuracy of their data. Future work will include contacting the authors of the CONSORT-EHEALTH checklist to propose these suggestions.

There was a great interest from trialists to learn more about the tracking methods available so further work could include publishing the findings from the tracking web usage project and the TRACK study. Recommendations from trialists on the topic of usage and engagement from the focus group study may also be beneficial to other trialists. Therefore, due to the novelty and usefulness of the gathered findings and recommendations from the studies, the author would like to disseminate those to the wider trial community further via publication and conference presentations.

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Appendices

Appendix 1: List of studies included in systematic review

1. Nina Charlotte Balk-Møller, Sanne Kellebjerg Poulsen, Thomas Meinert Larsen, “Effect of a Nine-Month Web- and App-Based Workplace Intervention to Promote Healthy Lifestyle and Weight Loss for Employees in the Social Welfare and Health Care Sector: A Randomized Controlled Trial”.

2. Marina Christoforou, José Andrés Sáez Fonseca, Elias Tsakanikos, “Two Novel Cognitive Behavioral Therapy–Based Mobile Apps for Agoraphobia: Randomized Controlled Trial”.

3. Tracy Comans, Gabor Mihala, Leanne Sakzewski, Roslyn N Boyd, Paul Scuffham, “The cost-effectiveness of a web-based multimodal therapy for unilateral cerebral palsy: the Mitii randomized controlled trial”.

4. Erik Forsell, Marie Bendix, Fredrik Holländare, Barbara Szymanska von Schultz, Josefine Nasiell, Margareta Blomdahl-Wetterholm, Caroline Eriksson, Sara Kvarned, Johanna Lindau van der Linden, Elin Söderberg, Jussi Jokinen, Katarina Wide, Viktor Kaldo, “Internet delivered cognitive behavior therapy for antenatal depression: A randomised controlled trial”.

5. Suzanne Lokman, Stephanie S Leone, Marion Sommers-Spijkerman, Agnes van der Poel, Filip Smit, Brigitte Boon, ” Complaint-Directed Mini-Interventions for Depressive Complaints: A Randomized Controlled Trial of Unguided Web-Based Self-Hel Interventions”.

6. Fadi M. Al-Silwadi, Daljit S. Gill, Aviva Petrie, Susan J. Cunningham, “Effect of social media in improving knowledge among patients having fixed appliance orthodontic treatment: A single-center randomized controlled trial”.

7. Johanna Schröder, Lena Jelinek, Steffen Moritz, “A randomized controlled trial of a transdiagnostic Internet intervention for individuals with panic and phobias - One size fits all”.

8. Karin van Rosmalen-Nooijens, Sylvie Lo Fo Wong, Judith Prins, Toine Lagro-Janssen, “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”.

9. Stephanie Alley, Cally Jennings, Ronald C Plotnikoff, Corneel Vandelanotte, “Web-Based Video-Coaching to Assist an Automated Computer-Tailored Physical Activity Intervention for Inactive Adults: A Randomized Controlled Trial”.

10. Rebekah K. Hersch, Royer F. Cook, Diane K. Deitz, Seth Kaplan, Daniel Hughes, Mary Ann Friesen, Maria Vezina, “Reducing Nurses’ Stress: A Randomized Controlled Trial of a Web-Based Stress Management Program for Nurses”.

11. Melinda Jane Hutchesson, Chor Yin Tan, Philip Morgan, Robin Callister, Clare Collins, ”Enhancement of Self-Monitoring in a Web-Based Weight Loss Program by Extra Individualized Feedback and Reminders: Randomized Trial”.

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15. C. Barr Taylor, Andrea E. Kass, Mickey Trockel, Darby Cunning, Hannah Weisman, Jakki Bailey, Meghan Sinton, Vandana Aspen, Kenneth Schecthman, Corinna Jacobi and Denise E. Wilfley, “Reducing Eating Disorder Onset in a Very High Risk Sample with Significant Comorbid Depression: A Randomized Controlled Trial”.

16. Helané Wahbeh, Elena Goodrich, Barry S. Oken, “Internet mindfulness meditation for cognition and mood in older adults: a pilot study”.

17. Claes Andersson, “Comparison of WEB and Interactive Voice Response (IVR) Methods for Delivering Brief Alcohol Interventions to Hazardous-Drinking University Students: A Randomized Controlled Trial”.

18. Cristina Cabrera-Muffly, Paul C. Bryson, Kevin J. Sykes, Yelizaveta Shnayder, ”Free Online Otolaryngology Educational Modules A Pilot Study”.

19. David Cameron, Tracy Epton, Paul Norman, Paschal Sheeran, Peter R. Harris, Thomas L. Webb, Steven A. Julious, Alan Brennan, Chloe Thomas, Andrea Petroczi, Declan Naughton and Iltaf Shah, “A theory-based online health behavior intervention for new university students (U@Uni:LifeGuide): results from a repeat randomized controlled trial”.

20. Constance Guille, Zhuo Zhao, John Krystal, Breck Nichols, Kathleen Brady, Srijan Sen, “Web-Based Cognitive Behavioral Therapy Intervention for the Prevention of Suicidal Ideation in Medical Interns: A Randomized Controlled Trial”.

21. Christine Knaevelsrud, Janine Brand, Alfred Lange, Jeroen Ruwaard, Birgit Wagner, “Web-Based Psychotherapy for Posttraumatic Stress Disorder in War-Traumatized Arab Patients: Randomized Controlled Trial”.

22. Sue Lauder, Andrea Chester, David Castle, Seetal Dodd, Emma Gliddon, Lesley Berk, James Chamberlain, Britt Klein, Monica Gilbert, David W Austin, Michael Berk, “A randomized head to head trial of MoodSwings.net.au: An internet based self-help program for bipolar disorder”.

23. Robert R Morris, Stephen M Schueller, Rosalind W Picard, “Efficacy of a Web-Based, Crowdsourced Peer-To-Peer Cognitive Reappraisal Platform for Depression: Randomized Controlled Trial”.

24. Amutha Ramadas, Carina Ka Yee Chan, Brian Oldenburg, Zanariah Hussein and Kia Fatt Quek, “Randomised-controlled trial of a web-based dietary intervention for patients with type 2 diabetes: changes in health cognitions and glycemic control”.

25. Jerod L. Stapleton, Sharon L. Manne, Katie Darabos, Kathryn Greene, Anne E. Ray, Amber L. Turner, Elliot J. Coups, “Randomized Controlled Trial of a Web-based Indoor Tanning Intervention: Acceptability and Preliminary Outcomes”.

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27. Anne C van der Gugten, Cuno SPM Uiterwaal, Theo JM Verheij and Cornelis K van der Ent, “E-health and consultation rates for respiratory illnesses in infants: a randomised clinical trial in primary care”.

28. Daniëlle Volker, Moniek C Zijlstra-Vlasveld, Johannes R Anema, Aartjan TF Beekman, Evelien PM Brouwers, Wilco HM Emons, A Gijsbert C van Lomwel, Christina M van der Feltz-Cornelis, “Effectiveness of a Blended Web-Based Intervention on Return to Work for Sick-Listed Employees with Common Mental Disorders: Results of a Cluster Randomized Controlled Trial”.

29. Michel Jean Louis Walthouwer, Anke Oenema, Lilian Lechner, Hein de Vries, “Use and Effectiveness of a Video- and Text-Driven Web-Based Computer-Tailored Intervention: Randomized Controlled Trial “.

30. Marian Wilson, John M. Roll, Cynthia Corbett, Celestina Barbosa-Leiker, “Empowering Patients with Persistent Pain Using an Internet-based Self-Management Program”.

31. Lilas Ali, Barbro Krevers, Nils Sjöström, Ingela Skärsäter, “Effectiveness of web-based versus folder support interventions for young informal carers of persons with mental illness: A randomized controlled trial”.

32. Erin O'Carroll Bantum, Cheryl L Albright, Kami K White, Jeffrey L Berenberg, Gabriela Layi, Phillip L Ritter, Diana Laurent, Katy Plant, Kate Lorig, “Surviving and Thriving with Cancer Using a Web-Based Health Behavior Change Intervention: Randomized Controlled Trial”.

33. Johanna Boettcher, Viktor Åström, Daniel Påhlsson, Ola Schenström, Gerhard Andersson, Per Carlbring, “Internet-Based Mindfulness Treatment for Anxiety Disorders: A Randomized Controlled Trial”.

34. Elin Børøsund, Milada Cvancarova, Shirley M Moore, Mirjam Ekstedt, Cornelia M Ruland, “Comparing Effects in Regular Practice of E-Communication and Web-Based Self-Management Support Among Breast Cancer Patients: Preliminary Results from a Randomized Controlled Trial”.

35. Heidi S. Donovan, Sandra E. Ward, Susan Sereika, Judith Knapp, Paula Sherwood, Catherine M. Bender, Robert P. Edwards, Margaret Fields and Renee Ingel, “Web-Based Symptom Management for Women with Recurrent Ovarian Cancer: A Pilot Randomized Controlled Trial of the WRITE Symptoms Intervention”.

36. Caroline L. Donovan, Sonja March, “Online CBT for preschool anxiety disorders: A randomised control trial”.

37. Tristan Gorrindo, Lydia Chevalier, Elizabeth Goldfarb, Bettina B. Hoeppner, Robert J. Birnbaum, “Autonomic Arousal and Learning in Web-Based Simulation: A Feasibility Study”.

38. Robin N Kok, Annemieke van Straten, Aartjan T F Beekman, Pim Cuijpers, “Short-Term Effectiveness of Web-Based Guided Self-Help for Phobic Outpatients: Randomized Controlled Trial”.

39. Myung Kyung Lee, Young Ho Yun, Hyeoun-Ae Park, Eun Sook Lee, Kyung Hae Jung, Dong-Young Noh, “A Web-based self-management exercise and diet intervention for breast cancer survivors: Pilot randomized controlled trial”.

40. Michael Mehring, Max Haag, Klaus Linde, Stefan Wagenpfeil, Antonius Schneider, “Effects of a Guided Web-Based Smoking Cessation Program with Telephone Counseling: A Cluster Randomized Controlled Trial”.

41. Elisabet Sundewall Thorén, Marie Öberg, Gunilla Wänström, Gerhard Andersson, Thomas Lunner, “A randomized controlled trial evaluating the effects of online rehabilitative intervention for adult hearing-aid users”.

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43. Clare L. Atzema, Peter C. Austin, Libo Wu, Michael Brzozowski, Michael J. Feldman, Michael McDonnell, Laurie Mazurik, “Speak Fast, Use Jargon, and Don’t Repeat Yourself: A Randomized Trial Assessing the Effectiveness of Online Videos to Supplement Emergency Department Discharge Instructions”.

44. Oksana Burford, Moyez Jiwa, Owen Carter, Richard Parsons, Delia Hendrie, “Internet-Based Photoaging Within Australian Pharmacies to Promote Smoking Cessation: Randomized Controlled Trial”.

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49. Amanda L Graham, Sarah Cha, Nathan K Cobb, Ye Fang, Raymond S Niaura, Aaron Mushro, “Impact of Seasonality on Recruitment, Retention, Adherence, and Outcomes in a Web-Based Smoking Cessation Intervention: Randomized Controlled Trial”.

50. R. Hurling, J-P. Claessen, J. Nicholson, F. Schäfer, C.C. Tomlin and C.F. Lowe, “Automated coaching to help parents increase their children’s brushing frequency: an exploratory trial”.

51. Brandon C Irwin, Deborah L Feltz, Norbert L Kerr, “Silence is Golden: Effect of Encouragement in Motivating the Weak Link in an Online Exercise Video Game”.

52. Ove K. Lintvedt, Kathleen M. Griffiths, Kristian Sørensen, Andreas R. østvik, Catharina E. A. Wang, Martin Eisemann and Knut Waterloo, “Evaluating the effectiveness and efficacy of unguided internet-based self-help intervention for the prevention of depression: a randomized controlled trial”.

53. Jeffrey Thiboutot, Christopher N Sciamanna, Bonita Falkner, Donna K Kephart, Heather L Stuckey, Alan M Adelman, William J Curry, Erik B Lehman, “Effects of a Web-Based Patient Activation Intervention to Overcome Clinical Inertia on Blood Pressure Control: Cluster Randomized Controlled Trial”.

54. Gabrielle Turner-McGrievy, Sri Kalyanaraman, Marci K. Campbell, “Delivering Health Information via Podcast or Web: Media Effects on Psychosocial and Physiological Responses”.

55. Wouter van Ballegooijen, Heleen Riper, Britt Klein, David Daniel Ebert, Jeannet Kramer, Peter Meulenbeek, Pim Cuijpers, “An Internet-Based Guided Self-Help Intervention for Panic Symptoms: Randomized Controlled Trial”.

56. Carolien A Wijsman, Rudi GJ Westendorp, Evert ALM Verhagen, Michael Catt, P Eline Slagboom, Anton JM de Craen, Karen Broekhuizen, Willem van Mechelen, Diana van Heemst, Frans van der Ouderaa, Simon P Mooijaart, “Effects of a Web-Based Intervention on Physical Activity and Metabolism in Older Adults: Randomized Controlled Trial”.

57 .E. Andersson, J. Enander, P. Andrèn, E. Hedman, B. Ljótsson, T. Hursti, J. Bergström, V. Kaldo, N. Lindefors, G. Andersson and C. Rück, “Internet-based cognitive behaviour therapy for obsessive–compulsive disorder: a randomized controlled trial”.

58. Gerhard Andersson, Per Carlbring, Tomas Furmark, “Therapist Experience and Knowledge Acquisition in Internet-Delivered CBT for Social Anxiety Disorder: A Randomized Controlled Trial”.

59. Manuel A. Franco-Martín, Mercedes Bernardo-Ramos, Felipe Soto-Pérez, “Cyber-Neuropsychology: Application of new technologies in neuropsychological evaluation”.

60. Deborah J Bowen, Patricia Nez Henderson, Jessica Harvill, Dedra Buchwald, “Short-term Effects of a Smoking Prevention Website in American Indian Youth”.

61. David N. Cavallo, Deborah F. Tate, Amy V. Ries, Jane D. Brown, Robert F. DeVellis and Alice S. Ammerman, “A Social Media–Based Physical Activity Intervention: A Randomized Controlled Trial”.

62. Heather L. Colleran, Cheryl A. Lovelady, “Use of MyPyramid Menu Planner for Moms in a Weight-Loss Intervention during Lactation”.

63. Colin A. Espie, Simon D. Kyle, Chris Williams, Jason C. Ong, Neil J. Douglas, Peter Hames, June S.L. Brown, “A Randomized, Placebo-Controlled Trial of Online Cognitive Behavioral Therapy for Chronic Insomnia Disorder Delivered via an Automated Media-Rich Web Application”.

64. Linda Fleisher, Venk Kandadai, Eileen Keenan, Suzanne M. Miller, Karthik Devarajan, Michele Rodoletz, Eric J. Bieber, David S. Weinberg, “Build It, and Will They Come? Unexpected Findings from a Study on a Web-Based Intervention to Improve Colorectal Cancer Screening”.

65. Evelien Heinrich, Jascha de Nooijer, Nicolaas C. Schaper , Maartje H.G. Schoonus-Spit, Monique A.J. Janssen, Nanne K. de Vries, “Evaluation of the web-based Diabetes Interactive Education Programme (DIEP) for patients with type 2 diabetes”.

66. Powell J, Hamborg T, Stallard N, Burls A, McSorley J, Bennett K, Griffiths KM, Christensen H, ”Effectiveness of a web-based cognitive-behavioral tool to improve mental well-being in the general population: randomized controlled trial”.

67. Lee M. Ritterband, Elaine T. Bailey, Frances P. Thorndike, Holly R. Lord, Leah V. Farrell, Lora D. Baum, “Initial evaluation of an Internet intervention to improve the sleep of cancer survivors with insomnia”.

68. Rianne van der Zanden, Jeannet Kramer, Rob Gerrits, Pim Cuijpers, “Effectiveness of an Online Group Course for Depression in Adolescents and Young Adults:A Randomized Trial”.

69. A. Blair Irvine, Laura Philips, John Seeley, Sara Wyant, Susan Duncan, Roger W. Moore, ”Get Moving: A Web Site That Increases Physical Activity of Sedentary Employees”.

70. Diana D. McDonnell, Gene Kazinets, Hyun-Ju Lee, Joel M. Moskowitz, “An Internet-Based Smoking Cessation Program for Korean Americans: Results From a Randomized Controlled Trial”.

71. Hendrika Meischke, Paula Lozano, Chuan Zhou, Michelle M. Garrison, Dimitri Christakis, “Engagement in “My Child’s Asthma”, an interactive web-based pediatric asthma management intervention”.

72. Deborah M. Miller, Shirley M. Moore, Robert J. Fox, Ashish Atreja, Alex Z. Fu, Jar-Chi Lee, Welf Saupe, Maria Stadtler, Swati Chakraborty, C.M. Harris, Richard A. Rudick, “Web-Based Self-Management for Patients with Multiple Sclerosis: A Practical, Randomized Trial”.

73. Anastasia Soureti, Peter Murray, Mark Cobain, Willem van Mechelen, Robert Hurling, “Web-Based Risk Communication and Planning in an Obese Population: Exploratory Study”.

74. Susan H. Spence, Caroline L. Donovan, Sonja March, Amanda Gamble, Renee E. Anderson, Samantha Prosser, Justin Kenardy, “A Randomized Controlled Trial of Online Versus Clinic-Based CBT for Adolescent Anxiety”.

75. Eric A. Storch, Nicole E. Caporino, Jessica R. Morgan, Adam B. Lewin, Ariz Rojas, Lindsay Brauer, Michael J. Larson, Tanya K. Murphy, “Preliminary investigation of web-camera delivered cognitive-behavioral therapy for youth with obsessive-compulsive disorder”.

76. Silje C Wangberg, Olav Nilsen, Konstantinos Antypas, Inger Torhild Gram, “Effect of Tailoring in an Internet-Based Intervention for Smoking Cessation: Randomized Controlled Trial”.

77. Gwen L. Alexander, Jennifer B. McClure, Josephine H. Calvi, George W. Divine, Melanie A. Stopponi, Sharon J. Rolnick, Jerianne Heimendinger, Dennis D. Tolsma, Kenneth Resnicow, Marci K. Campbell, Victor J. Strecher, Christine Cole Johnson, “A Randomized Clinical Trial Evaluating Online Interventions to Improve Fruit and Vegetable Consumption”.

78. Kelly M. Carpenter, Susan A. Stoner, Aneke N. Mikko, Lynn P. Dhanak, Jeffrey T. Parsons, “Efficacy of a Web-Based Intervention to Reduce Sexual Risk in Men Who Have Sex with Men”.

79. Saskia M. Kelders, Julia E.W.C. van Gemert-Pijnen, Andrea Werkman, Erwin R. Seydel, “Usage and Effect of a Web-based Intervention for the Prevention of Overweight: A RCT”.

80. Peter M. Neary, Robert Sung, Mark Corrigan, Maurice O’Donovan, Ronan A. Cahill and H. Paul Redmond, “The Benefits of an Interactive, Individualized Online Patient Pathway for Patients Undergoing Minimally Invasive Radioguided Parathyroidectomy: A Prospective, Double-Blinded, Randomized Clinical Trial”.

81. Caroline R Richardson, Lorraine R Buis, Adrienne W Janney, David E Goodrich, Ananda Sen, Michael L Hess, Kathleen S Mehari, Laurie A Fortlage, Paul J Resnick, Brian J Zikmund-Fisher, Victor J Strecher, John D Piette, “An Online Community Improves Adherence in an Internet-Mediated Walking Program. Part 1: Results of a Randomized Controlled Trial”.

82. Karolijne van der Houwen , Henk Schut, Jan van den Bout, Margaret Stroebe, Wolfgang Stroebe, “The efficacy of a brief internet-based self-help intervention for the bereaved”.

83. Sheana Bull, Katherine Pratte, Nancy Whitesell, Cornelis Rietmeijer, Mary McFarlane, “Effects of an Internet-based intervention for HIV Prevention: The Youthnet Trials”.

84. Kypros Kypri, Jonathan Hallett, Peter Howat, Alexandra McManus, Bruce Maycock, Steven Bowe, Nicholas J. Horton, “Randomized Controlled Trial of Proactive Web-Based Alcohol Screening and Brief Intervention for University Students”.

85. Gail Mc Vey Joanne, Gusella Stacey Tweed, Manuela Ferrari, “A Controlled Evaluation of Web-Based Training for Teachers and Public Health Practitioners on the Prevention of Eating Disorders”.

86. Sander M Slootmaker, Mai J M Chinapaw, Albertine J Schuit, Jacob C Seidell, Willem Van Mechelen, “Feasibility and Effectiveness of Online Physical Activity Advice Based on a Personal Activity Monitor: Randomized Controlled Trial”.

87. Miriam Wanner, Eva Martin-Diener, Charlotte Braun-Fahrländer, Georg Bauer, Brian W Martin, “Effectiveness of Active-Online, an Individually Tailored Physical Activity Intervention, in a Real-Life Setting: Randomized Controlled Trial”.

88. Håvar Brendryen, Filip Drozd, Pål Kraft, “A Digital Smoking Cessation Program Delivered Through Internet and Cell Phone Without Nicotine Replacement (Happy Ending): Randomized Controlled Trial”.

89. Emely de Vet, Jascha de Nooijer, Nanne K. de Vries and Johannes Brug, “Testing the transtheoretical model for fruit intake: comparing web-based tailored stage-matched and stage-mismatched feedback”.

90. Dominick L. Frosch, Vibha Bhatnagar, Steven Tally, Charles J. Hamori, Robert M. Kaplan, “A Randomized Controlled Trial Comparing Alternative Approaches for Men Considering Prostate Cancer Screening”.

91. Huong Q Nguyen, DorAnne Donesky-Cuenco, Seth Wolpin, Lynn F Reinke, Joshua O Benditt, Steven M Paul, Virginia Carrieri-Kohlman, “Randomized Controlled Trial of an Internet-Based Versus Face-to-Face Dyspnea Self-Management Program for Patients with Chronic Obstructive Pulmonary Disease: Pilot Study”.

92. Cameron D. Norman, Oonagh Maley, Xiaoqiang Li, Harvey A. Skinner, “Using the Internet to Assist Smoking Prevention and Cessation in Schools: A Randomized, Controlled Trial”.

93. R. T. Mangunkusumo, J. Brug, J. S. Duisterhout, H. J. de Koning and H. Raat, “Feasibility, acceptability, and quality of Internet-administered adolescent health promotion in a preventive-care setting”.

94. Barry G. Saver, David Gustafson, Thomas R. Taylor, Robert P. Hawkins, Nancy F. Woods, Susan Dinauer, Susan Casey, Aileen MacLaren-Loranger, “A tale of two studies: The importance of setting, subjects and context in two randomized, controlled trials of a web-based decision support for perimenopausal and postmenopausal health decisions”.

95. Chun-Ja Kim, Duck-Hee Kang, “Utility of a Web-based Intervention for Individuals with Type 2 Diabetes The Impact on Physical Activity Levels and Glycemic Control”.

96. Robin Mermelstein, Lindsey Turner, “Web-based support as an adjunct to group-based smoking cessation for adolescents”.

97. Kypros Kypri, Helena M. McAnally, “Randomized controlled trial of a web-based primary care intervention for multiple health risk behaviors”.

98. Kathleen M. Griffiths, Helen Christensen, Anthony F. Jorm, Kimberley Evans, Chloe Groves, “Effect of web-based depression literacy and cognitive-behavioural therapy interventions on stigmatising attitudes to depression: Randomised controlled trial”.

99. Rita Kukafka, Yves A. Lussier, M.D.Vimla L. Patel, James J. Cimino, “Web-based Tailoring and its Effect on Self-Efficacy: Results from The MI-HEART Randomized Controlled Trial”.

100. P. Dev, A.J.Winzelberg, A.Celio and C.B.Taylor, “Student Bodies: Psycho-Education Communities on the Web”.

Appendix 2: Data extraction form systematic review

Review of RCT literature to analyse web usage data

ID _____ **First author** _____

First year _____

Design Superiority Equivalence Non-inferiority

Other design features _____

Other _____

Clinical Area _____

Blinding

Not stated

None

Single _____

Double _____

If any blinding, specify who was blinded

Patient

Clinician

Assessor

Other

Trial online intervention

Internet (Web-based) _____ _____

Social media _____ _____

Mobile / Apps _____ _____

Internet plus additional element _____ _____

Other _____

Classify control arms

What was the control intervention?

Internet intervention

Non- Internet intervention

Waiting group

No intervention

Other _____

Were any online intervention changes reported?

If yes, indicate whether these changes were protocol departures/according to protocol

No

Yes: Online Intervention switches to alternative arm

Online Intervention switches to non- online intervention

Online Intervention prematurely terminated

Other _____

CONSORT flow diagram

No

Yes: The flow of patients in CONSORT flow diagram

_____

If yes, did they use e-CONSORT guidelines

No

Yes

Did trialists attempts to measure whether participants used online intervention?

If yes, which method they were using?

No

Yes: GA diagnostic

Software Tools

Server log data

Other _____

Did trialists make any attempt to check on reliability of methods used to record web usage data?

No

Yes _____

How the participants were told to use the intervention?

Not stated

Face-to-face instructions only

Email instructions only

Online/website information

Combined instructions

Other _____

What was the prescribed online dose?

Unspecified

Specified

Other _____

If specified, what was the prescribed dose?

_____

Methods of analysis stated in the methods

Indicate which was the primary analysis, and which method was used for efficacy and safety data (if specified).

ITT

PP

ITT and other analysis

Other _____

Was any specific adjustment made for intervention engagement and/or non-compliance for any outcomes in the analysis?

No

Yes _____

If yes, indicate

method of adjustment _____

whether adjusted analysis was for primary or secondary outcome

_____

whether adjusted analysis was for efficacy or safety outcome

_____

type of outcome that was included in adjusted analysis (e.g. binary, continuous, time to event)

_____

whether adjustment altered the conclusions of the analysis

_____

Did they report rate of missing primary outcome data?

If yes, specify rates of missing data (missing primary outcomes data)

No

Yes

_____

Appendix 3: Survey questions TRACK study

TRACK survey

Introduction

Many thanks for agreeing to help us with the TRACK study.

The TRACK study aims to explore trialists' experiences in the implementation and data obtained of tracking methods implemented in web-based interventions.

We would like to gather in-depth information about trialists' experience of using tracking methods including: the reasons for choosing a particular method; ease of implementation and use; and the costs associated with the tracking methods.

Providing such insight into tracking methods would be beneficial for other trialists when deciding which tracking method would be the most appropriate to use for tracking participants' engagement with web-based interventions.

Findings from the TRACK study will be a part of a PhD thesis. These findings may be written up for publication in an open access, peer-review journal and may be presented at relevant medical conferences.

Participation consent

I give my consent to participate in the survey and I confirm that I have read and understood the information sheet (version 1.0 01/07/2020) for the study.

I understand that my participation is voluntary and that I am free to withdraw from the TRACK Study at any time, without giving a reason.

I understand that brief quotations from some open-ended responses may be included in study reports. I understand that nobody will be able to identify me in these reports or papers.

I agree to data from my survey being stored at the University of Liverpool for 10 years after the end of this study for checking purposes. I understand that these will be stored securely in compliance with the Data Protection Act 2018.

Do you agree with the statements below?

- ○ I agree
- ○ I do not agree

I would like… Optional

- ☐ To receive a summary of the findings at the end of the study
- ☐ To be contacted about any future related studies

Please enter your email address

General Demographic Questions

Please specify your country of residence (country of residence while being involved in the study):

What is your job role (your job role while being involved in the study)?

- Trial manager
- IT personnel
- Chief investigator
- Other

If you selected other, please specify:

Reasons for choosing the tracking method

Did you undertake any research into which tracking method would be most suitable for your project?

- ○ Yes
- ○ No

What type of research did you undertake?

- ☐ I researched the tracking method online
- ☐ I consulted other trialists who have experience using the tracking method
- ☐ Other

If you selected Other, please specify:

What tracking method/s have you used to track patients' web usage (to track patients' engagement with the intervention)?

- ☐ Google Analytics / Universal Analytics
- ☐ Server logs
- ☐ Matomo
- ☐ Open Web Analytics
- ☐ Snowplow
- ☐ Amplitude
- ☐ Other

If you selected Other, please specify:

If you selected more than one method please indicate the first tracking method for which you will answer the questions.

Was this the first time you used this tracking method?

- Yes
- No

What was the reason/s for choosing this tracking method?

- This method was recommended to me
- I did online research for this method and the reviews were excellent
- It was free to use this tracking method
- Data storage capabilities of the method (for example, data stored for unlimited time)
- Other

If you selected Other, please specify:

Did you consider using other tracking method?

- Yes
- No

Please specify which and tell us why you did not use this tracking method

Implementation of the tracking method

Who was responsible for implementing the tracking method?

- Me
- Someone else

Please tell us how was responsible

Ease of implementation of the tracking method

What was the most challenging part of the implementation? (please elaborate)

Did you include a testing phase to check whether web usage was tracked appropriately?

- Yes
- No

What type of testing was performed?

- Internal only testing
- As part of a pilot
- Internal and pilot

Is there anything else you wish to share about issues picked up in the testing phase?

Can you please explain why not?

Overall use of the tracking method

What were the advantages of using the tracking method?

What were the disadvantages of using the tracking method?

What usage metrics did you record? (select all that apply)

- [ ] Number of logins
- [ ] Time spent on site
- [ ] Page views
- [ ] External links clicked
- [ ] Page content viewed
- [ ] Device used
- [ ] Browser type
- [ ] Video views
- [ ] Duration of videos watched
- [ ] Modules completed
- [ ] Other

If you selected Other, please specify:

What were the data storage capabilities of the tracking method? (for how long data could have been stored using this method)

- ○ Data were stored for unlimited time
- ○ Data were stored for a certain duration

Please specify duration

- ○ <6 months
- ○ 6-12 months
- ○ 1-2 years
- ○ 2-5 years
- ○ 5-10 years
- ○ >10 years

What tools did you use to analyse the data?

- ☐ R
- ☐ SAS
- ☐ Stata
- ☐ Bespoke code
- ☐ Other

If you selected Other, please specify:

Did you use any libraries to assist with the analysis of these data?

- ○ Yes
- ○ No

Please specify which libraries

Were there any features that you would have liked to see in the tracking method used?

Is there anything that you wished you had known about the tracking method before implementation?

Would you use the same tracking method again if appropriate?

- Yes
- No

Can you explain why would you use this tracking method again?

Can you explain why would you not use this tracking method again?

Would you recommend using the tracking method to other trialists?

- Yes
- No

Please explain why you would recommend this method

Please explain why you would not recommend this method

Costs associated with the tracking method

Did you pay for the tracking method? (were any costs associated with the method i.e cost of using the tracking method, cost with implementing the tracking method, training costs, etc)

- Yes
- No

Type of software used

What type of software did you use?

- Commercial
- Open source
- Bespoke

Costs associated with the tracking method (commercial software)

Did the cost of the tracking method influence your decision to use this method?

- Yes
- No

Please indicate approximate cost of the tracking method

Were costs incurred to cover training for the implementation including time for self-learning?

- Yes
- No

Please indicate approximate cost

Were costs incurred for data extraction training including time for self-learning?

- Yes
- No

Please indicate approximate cost

Did you pay for the implementation?

- Yes
- No

Please indicate approximate cost

Were there any additional costs associated with maintenance (i.e. to make changes as the study progressed)?

- Yes
- No

Please indicate approximate cost

Were there any additional costs with the tracking method?

- Yes
- No

Please indicate approximate cost

Would you recommend paying for a tracking method?

- Yes
- No

Do you have any additional comments about the tracking method and your experience with it? Optional

Costs associated with the tracking method (open source software)

Did the cost of the tracking method influence your decision to use this method?

- Yes
- No

Please indicate approximate cost of the tracking method

Were costs incurred to train or learn how to configure and implement the tracking method?

- Yes
- No

Please indicate approximate cost

Were costs incurred associated with self-learning to extract data?

- Yes
- No

Please indicate approximate cost

Did you pay for the implementation?

- Yes
- No

Please indicate approximate cost

Were there any additional costs associated with maintenance (i.e. updates to deal with bugs, feature enhancements)?

- Yes
- No

Please indicate approximate cost

Were there any additional costs with the tracking method?

- Yes
- No

Please indicate approximate cost

Would you recommend paying for a tracking method?

- Yes
- No

Do you have any additional comments about the tracking method and your experience with it? Optional

Costs associated with the tracking method (bespoke software)

Did the cost of the tracking method influence your decision to use this method?

- Yes
- No

What was the cost of developing the software?

Were there any costs associated with maintenance?

- Yes
- No

Please indicate approximate cost

Were there any additional costs with the tracking method (i.e. if the developer moved on and needed to be replaced, any training costs, cost to buy a book for training, extra time to read and investigate when developing the code?

- Yes
- No

Please indicate approximate cost

Would you recommend paying for a tracking method?

- Yes
- No

Do you have any additional comments about the tracking method and your experience with it? Optional

No costs associated with the tracking method

Do you think that using a free method was the best option or would an investment in a tracking method would have brought better results?

- Using a free tracking method was the best option
- Paying for a tracking method would have potentially brought better results
- Unsure

Do you have any additional comments about the tracking method and your experience with it? Optional

Multiple methods

Did you select using second tracking method?

- Yes
- No

If “Yes” participants were directed to answer same questions for additional methods.

Final page

Thank you for submitting your responses!

Appendix 4: Interview topic guide TRACK study

Interview Topic Guide

(Draft- this topic guide will be developed iteratively during the study)

Please note: ***Italic text indicates instruction for the PhD student and will not be read to participant***

Intro: My name is [*PhD student name*] and I am a PhD student at the University of Liverpool. Many thanks for agreeing to help us with the TRACK study.

Before we begin the interview I need to obtain your consent for the study is that ok? *(Refer to instructions (in box) on the Participant Consent form including consent for audio/video recording of this discussion).*

- **Obtain consent here**

You can stop the interview at any time. Before we start do you have any questions?

Have you had chance to look at the draft participant information sheet I sent to you for the TRACK study? (*If no- read through sheet with trialist*)

Section 1: General Demographic Questions	
1.1	Before we start I would like to ask you a few demographic questions. Can you please specify your country of residence while being involved in the study?
1.2	Can you tell me your job role while being involved in the study?
Section:2 Reasons for choosing the tracking method	
2.1	I've read your publication and I know that you tracked web usage in web-based intervention as part of a RCT. If they stated tracking method: You stated that you used [*tracking method stated in publication*] is that right? If they didn't state tracking method: What tracking method/s have you used to track patients' web usage?
2.2	Did you undertake any research into which tracking method would be most suitable for your project? (*Explore if they did online search on reviews of the tracking method, literature review or consulted someone for an opinion*)

2.3	Could you tell me why you/trial team decided on this tracking method, was there any particular reason?
2.4	Had you used this tracking method before this trial or was this your first experience of using it? (*Explore details of all tracking methods used and for what purpose*.)
2.5	Did you consider using any other tracking method? (*Explore why others were not used, mention other tracking methods*)
Section 3: Ease of implementation of the tracking method	
3.1	Who was responsible for implementing the tracking method?
3.2	What was the most challenging part of the implementation?
3.3	Did you include a testing phase to check whether web usage was tracked appropriately? If yes: Could you tell me a bit more, how did you check if web usage was tracked accurately? (*Prompt, how did you check the reliability of the tracking method used?*) If not: Can you please explain why not?
Section 4: Overall use of the tracking method	
4.1	What were the advantages and disadvantages of using the tracking method?
4.2	What usage metrics did you record? (*Prompt, did you record the number of logins, time spent on site, page views, external links clicked, page content viewed, device used, browser type, video views, duration of videos watched, modules completed etc.*)
4.3	What were the data storage capabilities of the tracking method? (*Prompt, was data stored for a limited or unlimited time and did the data storage capabilities of the method influenced the decision to choose this tracking method*)
4.4	What tools did you use to analyse the data (e.g. R, SAS, Stata, Bespoke code)?
4.5	Did you use any libraries to assist with the analysis of these data?
4.6	Were there any features that you would have liked to see in the tracking method used?
4.7	Is there anything that you wished you had known about the tracking method before implementation?
4.8	Would you use the same tracking method again if appropriate?
4.9	Would you recommend using the tracking method to other trialists?
Section 5: Costs associated with the tracking method	

5.1	Did you pay for the tracking method? *(If mentioned earlier say "You mentioned you paid for the tracking method" and ask the question below)*
5.2	If paid: Did the cost of the tracking method influence your decision to use this method?
5.3	If paid (commercial): Were costs incurred to cover training for the implementation including time for self-learning? Were costs incurred for data extraction training including time for self-learning? Did you pay for the implementation? Were there any additional costs associated with maintenance (i.e. to make changes as the study progressed)? Were there any additional costs with the tracking method? (*Prompt, explore costs associated with the tracking method*)
5.4	If paid (open source): Were costs incurred to train or learn how to configure and implement the tracking method? Were costs incurred associated with self-learning to extract data? Were there any additional costs associated with maintenance (i.e. updates to deal with bugs, feature enhancements)? Were there any additional costs with the tracking method? (*Prompt, explore costs associated with the tracking method*)
5.5	If paid (bespoke): What was the cost of developing the software? Were there any costs associated with maintenance? Were there any additional costs with the tracking method (i.e. if the developer moved on and needed to be replaced? (*Prompt, explore costs associated with the tracking method*)
5.6	If paid: Would you recommend paying for a tracking method? If not paid: Do you think that using a free tracking method was the best option or would an investment in a tracking method would have brought better results?
5.7	Do you have any additional comments about the tracking method and your experience with it?
I have no more questions	

Appendix 5: Invitation letter TRACK study

Invitation email 1

Dear [*corresponding author title and name*],

My name is Elena and I am a PhD researcher at the University of Liverpool. Web usage data in clinical trials are the focus of my PhD and I am currently conducting a study titled "Investigating trial teams' experiences of using tracking methods for web-based interventions".

As stated in your published study [*title of the study*], you tracked web usage in a web-based intervention as part of a randomised controlled trial. As a corresponding author I am contacting you to enquire if you were involved in tracking web usage in the trial, and if so, I would like to invite you to take part in an interview to discuss your views and experiences. Interviews will last approximately 30-60 minutes and can be conducted on a web-based platform (e.g Microsoft teams or Zoom) or over the telephone. Attached is the Study Participant Information Sheet.

If you were not involved in the web usage tracking I would be grateful if you can let me know of the name and contact details of the trialist/s involved so I can invite them to take part in the study.

If you have any questions please do not hesitate to contact me.

Thank you for reading this email,

Best wishes,

Elena Koneska

Invitation email 2

Dear [*member of the trial title and name*],

My name is Elena and I am a PhD researcher at the University of Liverpool. Web usage data in clinical trials are the focus of my PhD and I am currently conducting a study titled "Investigating trial teams' experiences of using tracking methods for web-based interventions".

[*name of the corresponding author in the study*] recommended to contact you as you were a key person involved in tracking web usage in [*name of study*].

We would like to invite you to take part in an interview to discuss your views and experiences. Interviews will last approximately 30-60 minutes and can be conducted on a web-based platform (e.g Microsoft teams or Zoom) or over the telephone. Attached is the Study Participant Information Sheet.

If you have any questions please do not hesitate to contact me.

Thank you for reading this email,

Best wishes,

Elena Koneska

Appendix 6: Participant Information Sheet TRACK study

The TRACK study

Participant Information Sheet

You are being invited to take part in a research study. Please ask us if there is anything that is not clear in this information sheet or if you would like more information (contact details overleaf).

When a trial participant visits and navigates on a clinical trial website which involves a web-based intervention, they may perform different interactions, such as viewing modules or videos, completing assignments or tasks, downloading documents or accessing subpages. These interactions can be tracked using different methods, providing valuable information to the trialists about the trial participants' engagement with the web-based intervention. This information on engagement is crucial to determine how web usage impacts on the participants' trial outcome.

Why have I been chosen?

It is my understanding that you have tracked participant interaction with a web-based intervention as part of a randomized controlled trial. As such, your views are very important to us.

We would like about 25 trialists to take part in an interview. We would be very grateful if you agreed to be one of them. The option of completing an online survey is available for those unable to take part in an interview.

What the interview and survey will cover?

The interview and the survey will cover:

- The reasons for choosing a particular tracking method, what influenced this decision, and how it was decided

- The implementation process of the tracking methods, including your views on the ease of the process
- The general use of the tracking method, including any features that enhanced the user experience or presented a problem for users
- The costs associated with the use of the tracking method

What will happen if I take part?

The interview can take place online (e.g. via Microsoft Teams or Zoom) or via telephone, whichever you prefer. The online interview will take about 30-60 minutes and will be conducted by Elena Koneska as part of her PhD research. With your permission we will audio/video record the interview. If you would prefer to take part in an online survey, a direct link to the survey will be sent via email.

What are the possible benefits and risks of taking part?

There are no anticipated risks with this study and it will not involve discussion of any personal or sensitive information. We cannot promise that you will benefit directly from this study, but many people find that taking part in studies of this sort is useful because they have a chance to air their views and to reflect on their work.

Should you want to discuss any aspect of the study, please contact Elena Koneska (details below).

Findings will form part of a PhD thesis. Recommendations based on study findings will aim to inform the future use of tracking methods.

What will happen with the data?

Data will be stored securely in compliance with the Data Protection Act 2018.

What will happen if I withdraw from the study?

You can withdraw from the study at any time, without giving a reason. You can choose to withdraw fully from the study, meaning there would be no further contact and all data collected up to that point would be removed from the study, or you can choose to withdraw

from further contact but allow us to retain and analyse all data collected up to that point.

Who is involved in this study?

Elena Koneska, a PhD student at the University of Liverpool is leading the study. She is supervised by Dr Susanna Dodd, Dr Duncan Appelbe (University of Oxford), Dr Kerry Woolfall, and Prof Paula Williamson.

What if there is a problem?

Any complaint about the conduct of this study, the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, then please contact Elena Koneska who will do her best to resolve the issue (see contact details below).

How to contact us

If you have any questions, please contact: Elena Koneska: Elena.Koneska@liverpool.ac.uk or Dr Susanna Dodd: shinds@liverpool.ac.uk.

Thank you for your time.

We are very grateful that you are considering taking part in this study.

Appendix 7: Reminder letter TRACK study

Follow up email

Dear [*corresponding author title and name*],

My name is Elena and I am a PhD researcher at the University of Liverpool. Web usage data in clinical trials are the focus of my PhD and I am currently conducting a study titled "Investigating trial teams' experiences of using tracking methods for web-based interventions".

As stated in your published study [*title of the study*], you tracked web usage in a web-based intervention as part of a randomised controlled trial. As a corresponding author we contacted you to enquire if you were involved in tracking web usage in the trial, and if so, to invite you to take part in an interview to discuss your views and experiences. Interviews will last approximately 30-60 minutes and can be on a web-based platform (e.g Microsoft teams or Zoom) or over the telephone. Attached is the Study Participant Information Sheet.

We would still like to invite you to participate in the interview. If you are not able to take part in the interview we would like to invite you to our online survey

https://liverpool.onlinesurveys.ac.uk/track-survey

The online survey should take 10-15 minutes to complete.

If you have any questions please do not hesitate to contact me.

Thank you for reading this email,

Best wishes,

Elena Koneska

Appendix 8: Participant Consent Form Interviews TRACK study

Elena Koneska
University of Liverpool
Block F, Waterhouse Building
Liverpool, L69 3GL
Email: Elena.Koneska@liverpool.ac.uk

TRACK Study Participant Consent Form

For the online interview the following would be explained to the participant: **I will read 8 statements to you in order to obtain your consent for the study. Please answer yes or no to each statement. I will then complete the form and send you a copy for your records. Is that ok? (Researcher tick (✓) AND initial when trialist say yes; if they do not agree leave blank).**

Is it ok with you if I audio/video record this consent taking for our records? If yes continue. If no, explain that we will not be able to proceed with the interview without recorded consent. (Thank the trialist for their time – interview end)

No.	Statement	Tick	Initial
1.	I confirm that I have read and understood the information sheet (version 1.0 dated 01/07/2020) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.		
2.	I agree to take part in an interview.		
3.	I agree to the interview being audio/video recorded.		
4.	I understand that my participation is voluntary and that I am free to withdraw from the TRACK Study at any time, without giving a reason.		
5.	I understand that brief quotations from some open-ended responses may be included in study reports. I understand that nobody will be able to identify me in these reports or papers.		
6.	I agree to data from my interview being stored at the University of Liverpool for 10 years after the end of this study for checking purposes. I understand that these will be stored securely in compliance with the Data Protection Act 2018.		
7.	I would like to receive a summary of the findings at the end of the study.(optional)		
8.	I would like to be contacted about any future related studies.(optional)		

Contact details (only needed if you have ticked and initialled statements 7 and/or 8)

Telephone number:

Email address:

Participant Full Name:

Today's Date: DD/MM/YYYY

To be completed by Researcher once the trialist representative has provided consent:

Researcher Full Name: **Researcher Signature:** **Today's Date:** DD/MM/YYYY

When completed, 1 (original) to be kept on record at the University of Liverpool, 1 copy to be sent to the participant after the interview

Appendix 9: Invitation emails focus group study

Invitation email 1

Dear [*corresponding author title and name*],

Thank you for participating in the TRACK study. As you expressed interest in potential future related studies I would like to invite you to take part in a focus group. The aim of the focus group is to explore your views and experience about usage and engagement with web-based interventions, determining engagement and how to encourage participants to engage with the intervention.

The focus group meeting will last approximately 60 minutes and will be conducted on a web-based platform (Zoom or Teams).

Explanation of the term “engagement” in reference to “adherence”. When referring to web-based interventions in particular there might not be a “prescribed dose” of intervention to which trial participants are randomised – i.e. the degree of use of the web-based intervention that they chose to engage with may well be optional. Because not all web-based interventions have a prescribed dose/threshold to which participants are expected to adhere, the term “adherence” may not be relevant. Therefore, we prefer to use the term “engagement” to measure the degree to which trial participants used the intervention.

If you have any questions please do not hesitate to contact me.

Thank you for reading this email,

Best wishes,

Elena Koneska

Invitation email 2

Dear [*corresponding author title and name*],

My name is Elena and I am a PhD researcher at the University of Liverpool. Web usage data in clinical trials are the focus of my PhD and I am currently conducting a study titled "Investigating measuring and encouraging usage of and engagement with web-based interventions: A focus group study".

As stated in your published study [*title of the study*], you tracked web usage in a web-based intervention as part of a randomised controlled trial. As a corresponding author I am contacting you to enquire if you were involved in tracking web usage in the trial, and if so, I would like to invite you to take part in a focus group. The aim of the focus group is to explore your views and experience about usage and engagement with web-based interventions, determining engagement and how to encourage participants to engage with the intervention.

The focus group meeting will last approximately 60 minutes and will be conducted on a web-based platform (Zoom or Teams).

Explanation of the term "engagement" in reference to "adherence". When referring to web-based interventions in particular there might not be a "prescribed dose" of intervention to which trial participants are randomised – i.e. the degree of use of the web-based intervention that they chose to engage with may well be optional. Because not all web-based interventions have a prescribed dose/threshold to which participants are expected to adhere, the term "adherence" may not be relevant. Therefore, we prefer to use the term "engagement" to measure the degree to which trial participants used the intervention.

If you have any questions please do not hesitate to contact me.

Thank you for reading this email,

Best wishes,

Elena Koneska

Appendix 10: Consent form focus group study

Elena Koneska
University of Liverpool
Block F, Waterhouse Building
Liverpool, L69 3GL
Email: Elena.Koneska@liverpool.ac.uk

Focus Group Participant Consent Form

Please read each statement and tick (✓) AND your initials if you agree. If you don't agree please leave blank.

No.	Statement	Tick	Initial
1.	I agree to take part in a focus group.		
2.	I agree the focus group meeting to be video recorded.		
3.	I understand that my participation is voluntary and that I am free to withdraw from the focus group at any time, without giving a reason.		
4.	I understand that brief quotations from some open-ended responses may be included in study reports. I understand that nobody will be able to identify me in these reports or papers.		
5.	I agree to data from the focus group meeting being stored at the University of Liverpool for 10 years after the end of this study for checking purposes. I understand that these will be stored securely in compliance with the Data Protection Act 2018.		
6.	I would like to receive a summary of the findings at the end of the study.(optional)		

Contact details (only needed if you have ticked and initialled statement 6)

Telephone number:

Email address:

Participant Full Name:

Today's Date: DD/MM/YYYY

To be completed by Researcher once the trialist representative has provided consent:

Researcher Full Name: **Researcher Signature:** **Today's Date:** DD/MM/YYYY

When completed, 1 (original) to be kept on record at the University of Liverpool, 1 copy to be sent to the participant after the interview

Appendix 11: Focus group topic guide

Topic guide focus group

(Researcher introduction) The aim of this focus group is to explore your views and experience about engagement with web-based interventions, determining engagement and how to encourage participants to engage with the intervention. We would also appreciate your views on recommendations and guidance for other researchers with regards to measuring and encouraging engagement with web-based interventions.

You have all provided consent for today's focus group and with your consent we will video record today's meeting. The recording will be transcribed and anonymised with all names and participant details removed. You can leave the meeting at any time.

Does anyone have any questions before we start?

Questions:

1. How did you measure participant engagement with the web-based intervention? (*Prompt, explore all usage metrics used to determine engagement.*)
2. If you have run a study using a web-based intervention what information on metrics do you wish that you had had before starting?
3. At the design stage of the web-based intervention would it have been useful to have had an understanding of the metrics that can be collected? (*Prompt, would have been helpful if you have known in advance which metrics can be collected?*)
4. What is the effect of the design (or features) of the web-based intervention on usage and engagement? (*Prompt, were there certain interactive features in particular that helped you to increase participant engagement with the web-based intervention?*)
5. Was there anything you wish you had known before starting your study with regards to participant usage and engagement with the web-based intervention? (*Prompt, was there anything that would have been helpful to know in order to encourage participants to engage more with the web-based intervention? Was there anything that would have made determining engagement more straightforward?)*
6. What are the most valuable lessons you have learned with regards to participant usage and engagement with web-based interventions? (*Prompt, what have you taken as a valuable experience with participant engagement that can be used for future web-based interventions?)*
7. What would you suggest researchers should do if participant engagement with a web-based intervention is low? (*Prompt, have you had an experience of low participant engagement with a web-based intervention and what would you recommend to avoid*

low engagement?) Follow up question "What in your opinion makes participants want to engage the most"?

Proposed recommendations

In the workshop, draft recommendations will be introduced by the researcher and interviewees will be asked: 'Do you have any initial comments or concerns about this recommendation? From your experience, what would need to be done to make it work? A follow up prompt would be: 'If this would not work, why not – and what would'?

The following recommendations would be presented to the interviewees.

1. Measures of engagement can vary per web-based interventions and therefore investigators are recommended to carefully determine the type of usage metrics used to calculate engagement. For example, the measures of engagement should correlate to patterns and features of engagement initially assumed to benefit participants.[8]
2. To increase engagement by carefully designing the web-based interventions to include interactive and unique features (for example, option to contact health professional directly, motivators etc). Feedback from participants from previous trials to be taken on board in the design of the web-based interventions.
3. Current trends in technology should be explored and considered. To understand what people use currently that can be useful to implement to engage participants with web-based interventions. For example, to use current modern messengers such as WhatsApp or Viber for communication or reminders if suitable.

[8] Dodd et al, "A framework for the design, conduct and interpretation of randomised controlled trials in the presence of treatment changes", 2017