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Editorial

Infodemiology and Infoveillance: Framework for an Emerging Set of Public Health Informatics Methods to Analyze Search, Communication and Publication Behavior on the Internet

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Abstract

Infodemiology can be defined as the science of distribution and determinants of information in an electronic medium, specifically the Internet, or in a population, with the ultimate aim to inform public health and public policy. Infodemiology data can be collected and analyzed in near real time. Examples for infodemiology applications include: the analysis of queries from Internet search engines to predict disease outbreaks (eg. influenza); monitoring peoples' status updates on microblogs such as Twitter for syndromic surveillance; detecting and quantifying disparities in health information availability; identifying and monitoring of public health relevant publications on the Internet (eg. anti-vaccination sites, but also news articles or expert-curated outbreak reports); automated tools to measure information diffusion and knowledge translation, and tracking the effectiveness of health marketing campaigns. Moreover, analyzing how people search and navigate the Internet for health-related information, as well as how they communicate and share this information, can provide valuable insights into health-related behavior of populations. Seven years after the infodemiology concept was first introduced, this paper revisits the emerging fields of infodemiology and infoveillance and proposes an expanded framework, introducing some basic metrics such as information prevalence, concept occurrence ratios, and information incidence. The framework distinguishes supply-based applications (analyzing what is being published on the Internet, eg. on Web sites, newsgroups, blogs, microblogs and social media) from demand-based methods (search and navigation behavior), and further distinguishes passive from active infoveillance methods. Infodemiology metrics follow population health relevant events or predict them. Thus, these metrics and methods are potentially useful for public health practice and research, and should be further developed and standardized.

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KEYWORDS

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Classical and Recent Infodemiology Studies

> *The Internet has made measurable what was previously immeasurable: The distribution of health information in a population, tracking (in real time) health information trends over time, and identifying gaps between information supply and demand.* [1]
>
> *We need to build tools now to manage future infodemics. I would define an infodemic as an excessive amount of unfiltered information concerning a problem such that the solution is made more difficult.* [Gunther Eysenbach]

> *Count what is countable, measure what is measurable. What is not measurable, make measurable.* [Galileo Galilei]

A few weeks ago, a paper published in the journal Nature by scientists associated with Google made worldwide headlines: Ginsberg and colleagues discussed how monitoring search queries on Google can be used to predict influenza outbreaks in the United States [2]. Data from this study was used to develop the Google Flutrends application. What was frequently missed in lay media reports was the fact that this was not an entirely novel idea. In fact, exactly the same methods have been employed and evaluated at the Centre for Global eHealth Innovation since 2002, under the label “infodemiology”. An award-winning paper published in 2006 by Eysenbach was the first to show a correlation between influenza-related searches on Google and influenza cases occurring in the following week in Canada [1]. As Google did not share search data with external researchers, a “trick” was used to obtain these data: A keyword-triggered ad on Google was purchased, allowing access to statistics reflecting search and click behaviour of Google users. This pioneering study also showed that Internet searches preceded doctors’ visits to sentinel physicians by 1 week (a fact which was later also confirmed by the Ginsberg study), pointing to the circumstance that often people first consult the Internet before going to a doctor. As early as 2003, a similar methodology was employed to evaluate whether search behavior changed before the SARS outbreak; however, at that time “in our search term experiment it did not seem to be sensitive enough [to detect] SARS” [3]. These early studies have inspired and motivated others to explore correlations between search behavior, information on the Internet, and public health relevant events. Wilson and Brownstein published a paper suggesting that chatter on the Internet preceded official announcement of a Listeriosis outbreak [4]. A number of other studies have replicated findings from the Eysenbach study on the relationship between Internet search behavior and influenza incidence [2,5,6]. A seminal paper published by Cooper and colleagues in this journal explored the relationship between search behavior for cancer (information demand), cancer incidence, cancer mortality, and news coverage (information supply) [7].

These studies are part of a growing body of literature that has been called “infodemiology” or, if the primary aim is surveillance, “infoveillance” [8] studies—automated and continuous analysis of unstructured, free text information available on the Internet. This includes analysis of search engine queries (the “demand” side), but also what is being published on websites, blogs, etc (the “supply” side).

Seven years after the concept was first introduced [9], this paper revisits the emerging fields of infodemiology and infoveillance and proposes an expanded framework. This paper also aims to illustrate the potential by suggesting applications for syndromic surveillance and management of public health emergencies, quality monitoring of information on the Internet and infodemic management, knowledge translation, health communication, health marketing, and populomics, including collecting behavioral measures at a population level for public health policy and practice. To illustrate the potential applications further and to form a crystallization point for collaborations we are working on the Infovigil project at the Centre for Global eHealth Innovation, which is a system allowing researchers, public health professionals, and the public to collect and monitor some of the metrics described below.

Whether infodemiology indicators follow public health relevant events or predict them, the main thesis of this paper is that infodemiology metrics and methods are potentially useful and should be further developed and standardized.

What Is Infodemiology?

The term infodemiology is a portmanteau of information and epidemiology. Epidemiology—the science of distribution and determinants of disease in populations—provides researchers, public health professionals, and policy makers with the tools and the data to influence public health and policy decisions. Unfortunately, with traditional epidemiological data collection methods, such as population health surveys, cohort studies, registries etc, it often takes years or decades to inform policy makers about the impact of public health policy decisions on public health. Also, early detection methods of outbreaks or other health conditions are often based on clinical data, and there is no “real-time” data on preclinical events and behavior patterns in a population.

Infodemiology can be defined as the science of distribution and determinants of information in an electronic medium, specifically the Internet, or in a population, with the ultimate aim to inform public health and public policy.

Potential infodemiology indicators and metrics include automatically aggregated and analyzed data on the prevalence and patterns of information on websites and social media; metrics on the “chatter” in discussion groups, blogs, and microblogs (eg, Twitter); and activities on search engines, etc.

Changes in information and communication patterns on the Internet can be an (early) “symptom” of changes in population health [1,2,4-6]. Reversely, in other situations, changes in information and communication patterns can have a negative or positive impact on population health as, for example, in the case of an “outbreak” of misinformation [9] or a public health campaign. Regardless of the direction of the arrow of causation, infodemiology is rooted in the idea that—at least for some areas and applications—there is a relationship between population health on one hand, and information and communication patterns in electronic media on the other, and if it were possible to develop robust metrics or “infodemiology indicators” which reflected these information and communication patterns in real-time, then all kinds of useful public health applications could be developed.

Thus, one important goal of infodemiology research is to develop, collect, and evaluate metrics and indicators for information and communication patterns that have some relationship to epidemiological data, or are otherwise useful for public health and policy making.

The term infodemiology was initially used to suggest development of measures for what is being published on the Internet (what is now called “supply-based infodemiology”)

[9]. Much of the discussion in the late ’90s about the quality of health information on the Internet centered around the concern that low quality information on the Internet could be detrimental to public health [10], and it was in this context that the term was coined. For example, it is reasonable to assume that online campaigns by anti-vaccination groups have a real impact on vaccination rates and thus on health status. While we can measure the relationship between vaccination rates and health status, no sound methodologies exist to identify and track (automatically) the “prevalence” of information that leads to lower vaccination rates.

While "infodemiology" was first used in the context of analyzing the “supply side” (what is being published on the Web) [9], the scope of infodemiology now also includes “demand-based” infodemiology (ie, analyzing what people need and monitoring their health information seeking behavior) [1], because similar methods are employed.

Regardless of the source of information, infodemiology requires a set of novel methods for consumer and public health informatics to measure the epidemiology of information, describing and analyzing health information and communication patterns in electronic media (eg, on the Web). While it is conceivable that infodemiology metrics can also be obtained in the "offline-world", the focus on electronic media has a practical reason: Once information is available in electronic form, it can be automatically collected and analyzed. Supply- and demand-based infodemiology methods are similar in that they employ similar workflows and face similar problems: Selecting and filtering information (“concepts of interest”) from a large textual dataset, attempts to “understand” the information semantically (natural language processing), geocoding the information, and employing basic descriptive and analytical statistical methods, or more advanced temporospatial statistical methods to detect trends and clusters.

Using infodemiology data for surveillance purposes has been called “infoveillance” [8]. Infoveillance is important for both the supply and demand sides. Public health professionals want to know, for example, if there is a surge of misinformation on the Internet on vaccination, so that public health campaigns and “health marketing” efforts can effectively counterbalance the misinformation. Public health professionals also need to know about surges in information demand, be it to address “epidemics of fear” [3] by supplying the public with appropriate information, or to detect real disease outbreaks for which spikes in Internet searches or chatter in newsgroups and postings on microblogs (Twitter etc) may be an early predictor. Information on behavior change is itself an important intervention in the case of an outbreak, and tracking how effectively information is disseminated during a pandemic is another potential application.

In what follows, I will discuss supply-based indicators, demand-based indicators, and data sources in more detail. Together they form the vision for infodemiology, and also provide a blueprint for the Infovigil system.

Supply-Based Infodemiology Methods and Applications

Imagine a system which continuously monitors Internet postings (be they on websites, blogs, microblogs, including Twitter, social media, discussion board postings, or other publicly available sources), employing natural-language processing and other methods to classify the postings by topic and obtaining indicators on changes over time. We call such metrics *supply*-based infodemiology indicators.

Information (Concept) Prevalence

The most basic infodemiologic supply indicators are *information prevalence* and *information occurrence ratios* (or, perhaps more precisely, *concept prevalence* and *concept occurrence ratios*), measuring the absolute or relative number of occurrences of a certain keyword or concept in a pool of information. Note that we are talking about “keywords” if we simply look for the occurrence of certain terms, and "concepts" if we try to “understand” meaning, at a minimum combining multiple keywords to take into account synonyms.

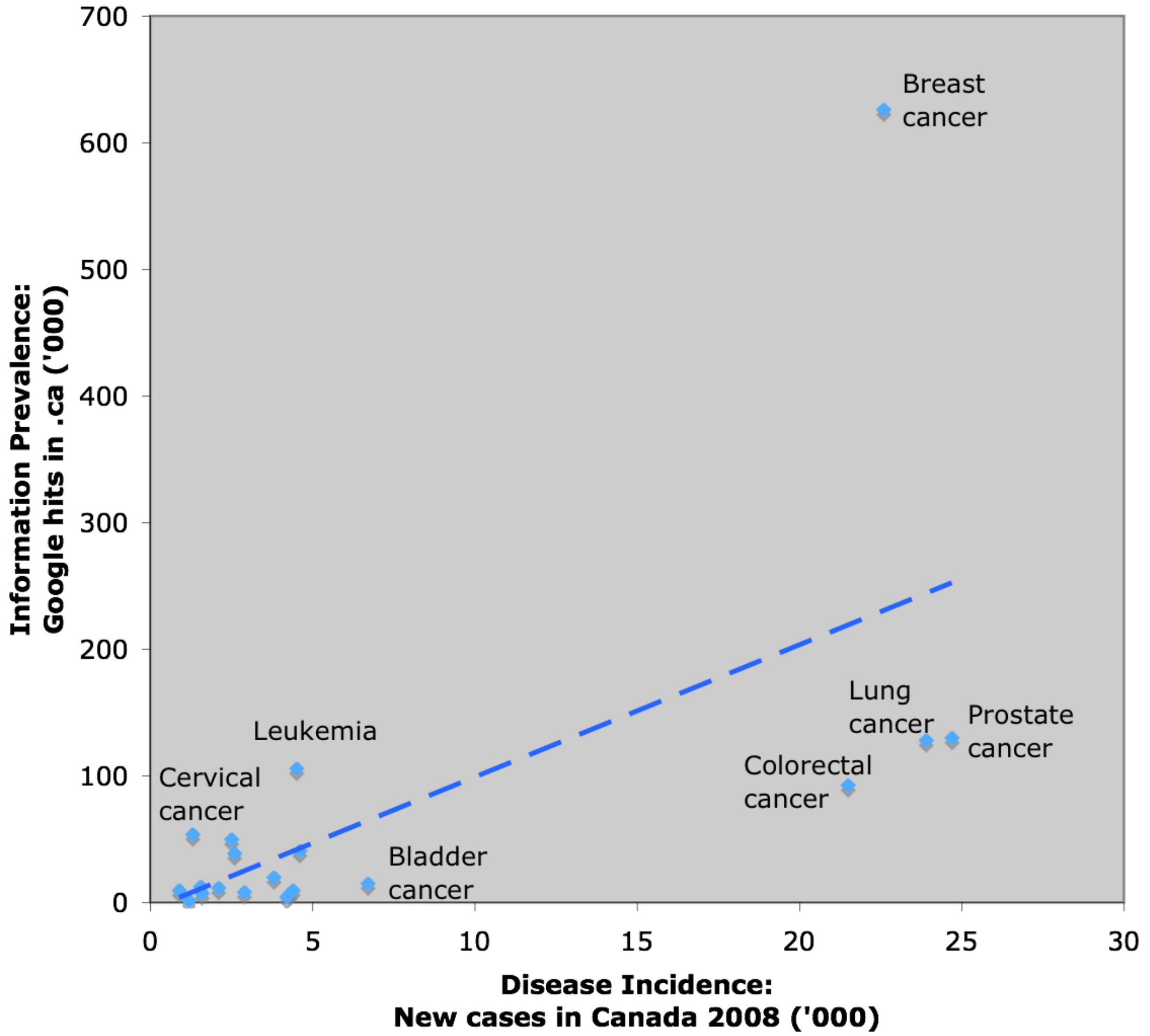
The “pool of information” can be a set of documents, postings, status lines (Twitter, Facebook), a collection of Web pages, or websites. For example, we could, automatically, obtain estimates of the (absolute) number of Internet postings about a certain topic identified by a set of keywords. We call these kinds of data *information prevalence.* To be more specific on how we obtained the prevalence we could also talk about *keyword prevalence* or *concept prevalence*.

Information prevalence data are particularly useful if we track them longitudinally (ie, track how the number of Internet postings on a given health-specific topic changes over time), as we would, for example, to see changes in relation to certain external events, such as a media campaign or a disease outbreak.

A crude method to obtain these *prevalence* indicators is to enter a search term (with a Boolean OR to include synonyms) into a search engine, which provides an absolute number of occurrences over time (see however the caveat on the reliability of search engines below). An occurrence can (depending on the search engine) be either the number of documents containing the search term at least once, or can be the number of term occurrences in the entire database (the unit does not really matter for our purpose, as long as we use the same method consistently). More advanced methods would also take into account synonyms and do a semantic search (ie, tracking concepts as opposed to keywords), and/or filter the searches to focus on specific geographical regions (for example countries).

Figure 1 illustrates the information prevalence of various cancers in the Canadian top-level domain (.ca) plotted against actual disease incidence (a cautionary note: these data on information prevalence are based on crude Google hits rather than semantic analyses). Such *information prevalence versus disease incidence* scatterplots (or other comparators, for example information prevalence versus mortality) may be useful to illustrate to policy makers in which areas there may be an information deficit. From a public health perspective, diseases and conditions which have a high incidence and high disease burden (mortality rate or impact on quality of life), and which are preventable or for which screening tests exist, should enjoy better "coverage" in the media and on the Internet than those which are not. Thus, it is not expected or desirable that there is a strict correlation between cancer incidence and information prevalence. However, Figure 1 illustrates that—compared to other forms of cancer with similar disease burden—breast cancer is an extreme outlier, pointing to a larger health care disparity between, for example, breast and prostate cancers (which have similar incidence and mortality, yet receive different levels of attention and funding), which has been previously referred to as the "prostate cancer gap" [11]. Policy makers need to be aware of such inequalities and information gaps, and there is a role for supply-based infodemiology indicators, both for management of chronic diseases, as well as for management of public health emergencies. An "infodemiology dashboard" could be developed which displays some of these metrics to inform policy makers for which areas health marketing media campaigns are required.

Figure 1. Information prevalence versus disease incidence scatterplot (Eysenbach, in preparation)

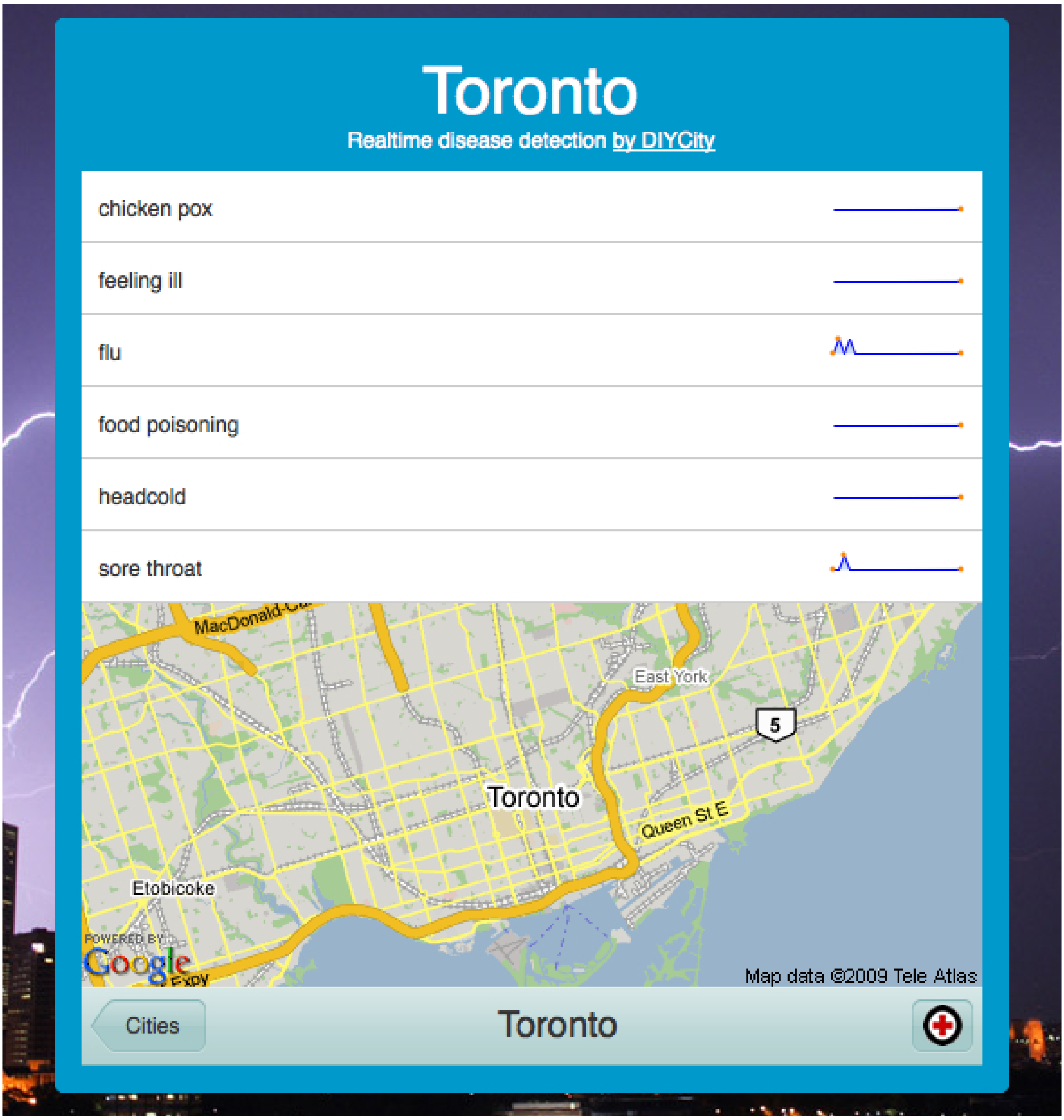


Information Incidence

As an analogy to the epidemiological terminology, we can also calculate information *incidence* rates, which determine the number of *new* information units created per unit of time. For example, comparing the incidence of Web pages which contain information about a certain topic, such as a new medical discovery, between countries, would provide interesting knowledge dissemination metrics.

Information or concept incidence rates may also point to emerging public health threats. For example, the Infovigil project monitors Twitter microblogs for mentionings of public health relevant keywords and phrases, such as "I have fever". Together with information on the location of the user, as well as automated conversations and directing users to surveys, these data can provide valuable information for public health agencies and the public alike. Figure 2 illustrates a very basic trend analysis of information incidence from Twitter feeds.

Figure 2. Information incidence (keyword occurrence) trends from Twitter status feeds ("tweets") (DIYCity/sickcity)



Information (Concept) Occurrence Ratios

As the number of websites is constantly increasing, absolute figures on information prevalence are less meaningful than normalized indicators (ie, relative indicators such as rates and ratios). If the total number of “information units” in the “pool of information” is known, then the denominator used to normalize the absolute count could simply be the total number of information units. For example, if we know that the Web has a total of x Web pages in a given language at a given point in time, and y of these pages deal with cancer, then we can express the information prevalence as the proportion y/x. However, in the case of the Web, the denominator, which would be the total number of all indexed files and documents (including, for example, html, excel, and powerpoint files etc) in the specific language of the numerator keywords, is often hard to obtain or not known. While search engines such as Google may have data on the total number of indexed documents in a certain language, this information is usually proprietary and not accessible to researchers.

Thus, it is often easier is to express the information prevalence as a fraction of information units about a certain topic compared to a control keyword or concept. For example, if the number of Web resources mentioning “prostate cancer” is 21.6 million, compared to 214 million resources mentioning cancer, then the occurrence ratio of prostate cancer to cancer is 21.6:214 = 10%.

Studying occurrence ratios may provide fascinating insights into the linguistic and cultural differences of the use of words and concepts between countries, but it may also be a method to study inequalities and differences in access to health information. Table 1 illustrates differences between the information occurrence ratios for “cervical cancer” information versus “cancer” information in Canada, the United Kingdom, and Australia. However, these are crude analyses based on keyword on Google. A proper infodemiological investigation would attempt to “understand” semantically the content of Web pages.

Another important caveat is that many search engines do not give accurate or reliable hit counts. Not only provide different search engines different results, but even the same search engine queried multiple times during the same day may give different estimates. Systems like Infovigil collect this information from different search engines on different times during the day, and employs statistical methods to even out discrepancies. This also minimizes the potential bias that changes to the number of hits for certain keywords could be confounded by changes in search engine algorithms. Alternative methods exist that can bypass search engines altogether, for example random IP sampling or the random creation of domain names, but these methods have their own set of problems, such as triggering security alerts as they resemble hacking attempts.

Table 1. Information occurrence ratios for various concepts in English-speaking industrialized countries

	Google.com (all country domains)	Canada (.ca on Google.com)	United Kingdom (.uk on Google.com)	Australia (.au on Google.com)
Hits (in Million)				
"cervical cancer"	7.09	0.08	0.41	0.05
Cancer	227	3.95	8.77	3.03
Health	1190	49.7	57.4	67.8
Disease	226	3.67	4.84	3.05
Illness	68.6	1.57	2.8	2.02
Wellness	147	3.4	1.67	0.74
Information Occurrence Ratios				
cervical cancer/cancer	0.03	0.02	0.05	0.02
disease/health	0.19	0.07	0.08	0.04
disease/wellness	1.54	1.08	2.90	4.12
illness/health	0.06	0.03	0.05	0.03
illness/wellness ratio	0.47	0.46	1.68	2.73

Concept Co-occurences

Looking for *co-occurrences* of different keywords or concepts (for example, a disease name and the name of a pharmaceutical substance) could provide *knowledge translation or innovation diffusion metrics*. For example, after publication of a trial confirming the effectiveness of a new drug in a medical journal, researchers could measure how long it takes for a new therapy to be acknowledged and taken up by the public, as reflected by the incidence of the disease term and the treatment concept occurring together. These indicators could in turn be useful to study different methods to accelerate knowledge translation (eg, publishing in open access journals, hosting workshops, holding press-conferences, and issuing press-releases, etc). Moreover, algorithms could be developed which monitor the medical, peer-reviewed literature, on the one hand, and the Internet, on the other, to collect and provide continuous real-time knowledge translation indicators.

While technically more challenging, it should also be possible to automatically identify and classify cases of misinformation or unbalanced information, tracking trends over time. For example, anti-vaccination websites use specific language, have specific attributes (eg, linking to other anti-vaccination sites), and cite a specific subset of the medical literature to provide a one-sided, biased view of the medical evidence [12]. A generic algorithm to obtain a measure for bias would, for example, be to compare the reference list of a systematic review to the references cited on a given website, which would enable researchers to quantify the direction and degree of content biases.

Once this information on the incidence of bias in a given field is collected in a longitudinal fashion, the effectiveness of public health and health marketing programs becomes measurable. For example, a media campaign addressing myths surrounding vaccination should lead to a change in the ratio of anti-vaccination postings to pro-vaccination statements, which in turn may be a predictor for changes in actual vaccination rates.

A final application area to be mentioned here is *policy implementation and evaluation*. As in the management adage which says, “one cannot manage what cannot be measured”, the case for gathering infodemiology data can be predicated on measuring the progress towards *policy objectives*, for example policies which address health information and health communication specifically related to the quality of information for the public. For example, the US public health policy document, “Healthy People 2010” [13] contained “[Increase of] quality of Internet health information sources” as an explicit policy objective (Objective 11-4). Other policy objectives (not from this document) may, for example, stipulate an increase of information written on a specific reading level, an increase of culturally sensitive health information for certain population groups or in certain languages (eg, minority languages). In most of these cases, it is conceivable that infodemiology methods could be developed and used to obtain and track indicators that would measure the progress towards such policy goals.

Identifying and Aggregating Public-Health Relevant Information from Secondary Sources

Another class of “supply-side” based applications, for example the Global Public Health Intelligence Network (GPHIN), the HealthMap System, and the EpiSPIDER Project, analyze selected secondary data sources, such as news reports and expert newsletters (ProMED mail), and aggregate public-health relevant information, in particular about infectious disease outbreaks [14]. These systems can be seen as tools for Open Source Intelligence (OSINT) collection. OSINT is intelligence that is “produced from publicly available information that is collected, exploited, and disseminated in a timely manner to an appropriate audience for the purpose of addressing a specific intelligence requirement” (Sec. 931 of Public Law 109-163, National Defense Authorization Act for Fiscal Year 2006). (Note that in this context “open source” refers to publicly available information, not to open source software.)

These systems usually use a more selective approach in terms of choosing high-quality, expert-curated secondary data sources, as opposed to systems such as the Infovigil system, which attempt to harness the “collective intelligence” of people on the Internet by analyzing noisier "primary data" on information supply and demand (eg, Twitter feeds or search and navigation behavior).

Identifying and Aggregating Public-Health Relevant Information on Social Networks

A final category of systems which could be developed would be systems which analyze and extract information from the Internet about the structure of social networks. For certain public health situations, especially in the case of an outbreak, but also for health marketing campaigns, it is advantageous to gather intelligence about the relationship between people. For example, it is conceivable that information on who knows whom from the friends-list on Facebook may help to contain the spread of an infectious agent if public health professionals have ready access to this information. Obviously, "knowing" somebody, communicating with someone, or being a "friend" with somebody on Facebook does not necessarily mean that these people have physical contact, hence, more advanced methods than just extracting the ""friends-list" from Facebook are required in order to be of use for public health.

Demand and Navigation Behavior-Based Infodemiology Methods and Applications

With demand-based infodemiology indicators we usually refer to data generated from the search and “click” (ie, navigation) behavior of people.

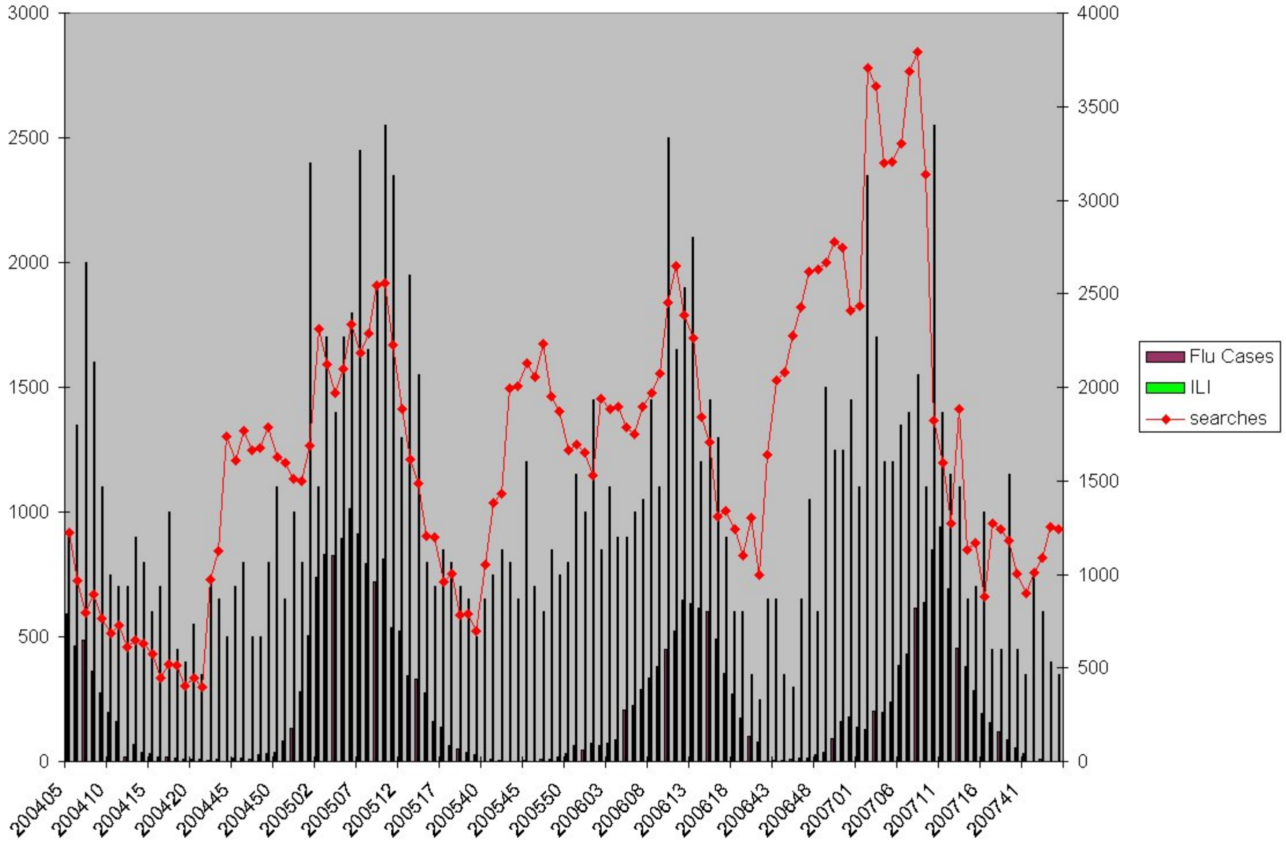
Potential data sources include data from search engines (something only the search engines themselves have access to), as well as search and navigation data from Website logs (individual sites or pooled from different sites), although the latter is heavily confounded by the content of the website and thus more difficult to analyze. A final possibility is to develop a browser-plugin or desktop software that—with a user’s explicit consent—transmits anonymized search and possibly navigation behavior to the Infovigil data centre.

Query log data from search engines allow valuable insights into information needs and human behavior. Typical query log data contain a unique user identifier (eg, a random number, which is set as a cookie in the user’s client browser, allowing it to associate searches which come from the same user) and/or an IP address for the user, query string, query time, and the click URL. The user identifier and the IP address are privacy sensitive information. It is possible to reconstruct the identity of a user from this information if either data is left in the logfiles [15]. However, even search data that has been stripped of this information can be useful enough to identify trends [1].

Examples of *demand prevalence indicators* which can be construed from these data are the number of searches on a specific topic coming from a specific region, or the number of clicks on websites with a specific topic. While search data alone are sometimes ambiguous and often do not allow inference with the intention of the user (somebody looking for the keyword “cold” doesn’t necessarily have cold symptoms), search data analyzed in conjunction with click data are much more meaningful (for example, somebody looking for the keyword “cold” and then clicking on a link that says something like “Click here for comprehensive information on what to do if you have cold symptoms”, or just clicking on a medical website providing influenza information, provides richer and more specific information on the presumed intention of the user). It has also been shown that click data (on an influenza-specific ad) are more predictive for influenza than search data [1].

Search engine data mining methods exist that can use and cluster query and click data so that meaningful inferences can be made on the presumed intention of the user [16].

Figure 3. Relationship between information demand (searches on Google), flu cases, and influenza-like illnesses reported by sentinel physicians. Partial data from a five-year prospective study harvesting search and click data from Google 2004-2007 (Eysenbach 2007, presented at AMIA Annual Fall Symposium, Chicago 2007, method as described in [1])



Active Methods Involving Consumers

The infodemiology and infoveillance methods outlined above can be referred to as passive methods, as they try to analyze and recognize trends on the Internet automatically and passively, without actively involving users. However, because the Internet is an interactive medium, there is also the potential to seamlessly collect even richer data from people, or to direct them to interventions. In the field of syndromic surveillance this represents nothing less than a paradigm shift, as traditional surveillance efforts, which are based, for example, on monitoring emergency room admissions or over-the-counter drug sales, happen without consumers even noticing it or being able to provide input. In contrast, using infoveillance methods, consumers can be directed to provide additional information. For example, when tracking search data for influenza specific keywords using the Google Ad method [1], it is possible to trigger an ad which leads to a quick online survey soliciting additional information from consumers. Similarly, postings in newsgroups or status updates on Twitter could trigger an automatic reply from an "infovigil robot" directing them to surveys or an intervention. Websites like whoissick.org or sicklike.me, which ask users to enter their symptoms, demonstrate that consumers are willing to actively participate in surveillance efforts by volunteering additional information.

Bringing it all Together: Relationship Between Health Information Supply, Demand, and Population Health

To date, only a few pioneering studies have explored the relationships between information supply and/or demand, on one hand, and population health, on the other hand, and have experimented with infodemiology metrics. As argued above, the development and standardization of these metrics is an emerging area of research, and, as shown above, the application areas of infodemiology metrics range from early disease detection, to prevention and chronic disease management on a population level, to policy development and implementation, and knowledge translation research. Bringing demand- and supply-indicators together could allow for fascinating insights into the dynamics and interactions between information provision and information seeking on a population level.

A final perspective comes from the behavioral sciences. Analyzing how people search and navigate the Internet for health-related information, as well as how they communicate and share this information, can provide valuable insights to health-related behavior of populations, including for example the level of understanding of health issues, knowledge about health-related conditions, and so on. Such information is traditionally collected through large and expensive population surveys such as the National Cancer Institute's "Health Information National Trends Survey" (HINTS), which ask participants to recall their behavior. While such surveys remain invaluable, infodemiology methods and metrics may complement these data by providing direct and honest data on health information seeking behavior, free from recall or social desirability biases, conducted in real time, and executed relatively cheaply.

This fits into the broader vision of “populomics”, a term used by Gibbons to propose the gathering of “population level data to enable the development of ‘community (population) arrays’ or community-wide risk profiles” [17].

In 2006, the US National Cancer Institute and the Office of Behavioral and Social Sciences started to push for the concept of “populomics” to take its place alongside “genomics” and “proteomics”, arguing that “it is crucial for national planning and team science to include common data elements from the behavioral sciences into national assessments of population health”. The NCI further argued that “behavioral measures are needed in the health care environment [...] and in public health planning, in which national indices of progress on behavioral measures could guide policy and communication planning” [18].

Infodemiology metrics which reflect the behavior of people on the Internet, including their health seeking behavior or their behavior change attempts, such as smoking cessation, physical activity, dietary changes, use of sunscreen, and reduction in alcohol consumption, evidenced by search and publication behavior, could represent novel and valuable measures for this purpose.

Conclusion

Infodemiology is an emerging discipline within public health informatics which characterizes a sign of our times: That it is not so much the availability of information that challenges us, but its aggregation and analysis. The field is highly interdisciplinary and requires the collaboration of information scientists, computer scientists, epidemiologists, medical experts, public health informatics experts, behavioral scientists, and statisticians. In fact, metrics and methods developed in other disciplines (infometrics, webometrics, and in the “open source intelligence” community) may have direct applications in infodemiology. Research partnerships with the private sector, for example search engines, is required. On the other hand, infodemiology also highlights threats to privacy and raises novel issues around informed consent, due to aggregation and analysis of openly accessible information about people on a large scale.

These challenges notwithstanding, the multitude of potential applications and benefits for society justify investments in infrastructure and research, and it is not least the peer-reviewers for funding agencies, philanthropical organizations, and medical journals which should keep an open mind to this novel and unconventional set of methods.

Conflicts of Interest

None declared.

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Original Paper

A Text Message–Based Intervention for Weight Loss: Randomized Controlled Trial

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Abstract

Background: To our knowledge, no studies have evaluated whether weight loss can be promoted in overweight adults through the use of an intervention that is largely based on daily SMS (Short Message Service: text) and MMS (Multimedia Message Service: small picture) messages transmitted via mobile phones.

Objective: This paper describes the development and evaluation of a text message–based intervention designed to help individuals lose or maintain weight over 4 months.

Methods: The study was a randomized controlled trial, with participants being exposed to one of the following two conditions, lasting 16 weeks: (1) receipt of monthly printed materials about weight control; (2) an intervention that included personalized SMS and MMS messages sent two to five times daily, printed materials, and brief monthly phone calls from a health counselor. The primary outcome was weight at the end of the intervention. A mixed-model repeated-measures analysis compared the effect of the intervention group to the comparison group on weight status over the 4-month intervention period. Analysis of covariance (ANCOVA) models examined weight change between baseline and 4 months after adjusting for baseline weight, sex, and age.

Results: A total of 75 overweight men and women were randomized into one of the two groups, and 65 signed the consent form, completed the baseline questionnaire, and were included in the analysis. At the end of 4 months, the intervention group (n = 33) lost more weight than the comparison group (−1.97 kg difference, 95% CI −0.34 to −3.60 kg, $P = .02$) after adjusting for sex and age. Intervention participants' adjusted average weight loss was 2.88 kg (3.16%). At the end of the study, 22 of 24 (92%) intervention participants stated that they would recommend the intervention for weight control to friends and family.

Conclusions: Text messages might prove to be a productive channel of communication to promote behaviors that support weight loss in overweight adults.

Trial Registration: Clinicaltrials.gov NCT00415870; http://clinicaltrials.gov/ct2/show/NCT00415870 (Archived by WebCite at http://www.webcitation.org/5dnolbkFt)

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KEYWORDS

Mobile phone; obesity; SMS; text message; health behavior

Introduction

The percentage of overweight (body mass index, or BMI, 25.0-29.9 kg/m^2) and obese (BMI $\geq$ 30 kg/m^2) adults has increased in the United States, from 43.3% in 1960 to 66.3% in 2003-04 [1]. Obesity increases the risk of cardiovascular disease [2] and overall mortality [3]. Weight loss as modest as 5% to 10% significantly improves the risk for several chronic diseases, such as hypertension [4], diabetes mellitus and insulin resistance [5], and selected cancers [6]. It has been known for over 30 years that a 10% reduction in weight corresponds to an approximate 20% reduction in coronary disease incidence, whereas a 10% increase in weight is associated with a 30% increase in incidence [7]. Thus, rather than requiring dramatic levels of weight loss, expert consensus is that lifestyle interventions that promote modest levels of sustained weight loss are likely to confer substantial health benefits [8].

Clinical and commercial weight loss programs can produce short-term weight loss, but a majority of adults regain about 40% of the lost weight in the first year and continue to regain [9]. Simple dietary restriction has not been associated with successful weight control [10]. Examining effective approaches to weight loss may be helpful for determining what behavioral skills should be promoted for weight loss and weight loss maintenance. Among these, self-monitoring has emerged as a critical skill for obesity management since those who report monitoring their weight on a daily or weekly basis have greater success in achieving weight loss goals [11,12]. Self-monitoring increases awareness of food and caloric intake, enhances self-efficacy, and allows for monitoring of progress and change over time [13]. However, detailed self-monitoring is labor intensive for participants and adherence is relatively low. One weight loss study found that while self-monitoring of food intake was rated as a useful strategy for weight loss, only 30% of participants continued this behavior after the study had ended [14]. Barriers such as stress, lack of social support, and discomfort with recording can affect adherence to self-monitoring [13].

Mobile phones may provide an opportunity to improve behaviors like self-monitoring, in particular through the use of Short Message Service (SMS), or text, messages. For example, sending text messages to mobile phones increased the effectiveness of a smoking cessation intervention among college students [15]. Another study among young adults in New Zealand revealed that participants who received text messages were more likely to quit smoking at 6 weeks compared to controls [16]. In a program conducted among youth with type 1 diabetes [17], daily text messages were helpful for disease self-management, increased self-efficacy, and treatment adherence and achieved high satisfaction among participants. In a randomized controlled trial of an Internet and mobile phone–based physical activity intervention among overweight adults that included reminders for exercise sessions sent via cell phone, experimental participants engaged in over 2 hours more physical activity per week than those with no access [18]. And, in an uncontrolled study among adults in South Korea, weekly text messages about diet, exercise, and behavior modification proved effective in promoting weight loss at 12 weeks [19]. To date and to our knowledge, there have been no studies on the use of daily text messages delivered via mobile phone as an intervention to address overweight among adults. Thus, we sought to determine if text messaging was a useful and effective strategy to help adults self-monitor their weight and improve weight outcomes. We hypothesized that, compared to overweight adults receiving standard weight control advice, those enrolled in a 4-month program that utilized daily text messages as a means of behavioral prompting, support, and self-monitoring would be more successful in their weight loss goals.

Methods

Formative Research

The study evaluated a mobile phone–based application designed as an assessment and intervention tool to improve dietary behaviors and reduce weight. Designing the system began with formative research with overweight men and women to solicit feedback about dietary behaviors, current mobile phone and text and picture message habits, the type and frequency of text and picture messages helpful for weight loss, and nutrition-related topic areas that should be included in a weight loss program. Focus group participants also tested prototypes of the system by receiving and responding to sample text and picture messages. While men and women differed on the preferred number of messages per day, both groups agreed that messages related to motivation, progress with weight loss, tips, and hints would be welcomed.

Intervention

The system was developed to be both personally tailored and interactive. Personal tailoring was accomplished by providing flexibility in the number and timing of receipt of messages each day. For example, users could choose different times during the day to receive a message—typically one in the morning and one in the evening, with one to three additional messages when the user thinks a reminder would be helpful. A database was developed of over 3000 SMS text and Multimedia Message Service (MMS; essentially small pictures) messages and 1500 rules that determined what message was sent based on the day of week, time of day, and the participant’s eating behaviors and previous replies, among other parameters. Approximately half of the messages requested a reply, with the balance providing tips, suggestions, and positive reinforcement or encouragement for improved behaviors. To minimize annoyance, the system was designed so if the user chose not to respond to a message, it reduced the number of messages requesting replies until a response was provided. Also, the user was given the opportunity to change the time and frequency of the messages after gaining experience with use of the system.

The intervention was organized by topics that changed each week as the participant proceeded through the intervention. The weekly topics included behavioral and dietary strategies known to positively influence weight control, including goal setting and self-monitoring, understanding calories, portion control, pedometers and physical activity, personal strategies for weight loss and overcoming barriers, volumetrics (consuming foods that are healthy and make one feel “full”), replacement and substitution, routine physical activity, organization and meal planning, strategies for eating out, strategies for creating healthy food and exercise environments, strength training, emotion eating, managing tough social situations, body image, and sticking with it. In addition to weekly topics, each week participants were instructed to weigh themselves, fill out worksheets outlining their food and exercise goals, and set goals for a daily 500 calorie reduction using the strategies provided in the corresponding weekly topic. For example, in week 3, participants learned about portion control. Also in week 3, participants were instructed to select portion control strategies that they would use in order to reduce their daily calories. To support self-monitoring, participants used the mobile phone to report their weight once a week. A graph of weight change was also sent to participants weekly.

To keep the text messaging novel and non-repetitive, the type and content of the messages sent throughout the week changed from day to day (Table 1), and participants never got the exact same message throughout the entire duration of the study. As an example, a person requesting two daily messages, one in the morning and the other in the evening, might receive the following:

- a *topic* message on Monday, Wednesday, Thursday, and Saturday, such as "Control your portions by setting aside a large snack package into smaller bags or buy 100 calorie snack packs!"
- a *question* each day asking the participant to reply, such as "How often do you meal plan? A) Every day; D) Every now and then; G) Never." (A, D, and G were chosen to simplify the use of the key pad for responses since they required only one touch because phones commonly cluster three letters on each button, for example, ABC, DEF, GHI.)
- *tips* or *questions* on Tuesday, Friday, and Sunday that were tailored to the participant's eating behaviors

For example, a participant who was identified as having difficulty eating fruits and vegetables might get the text message tip "In a rush? Buy pre-cut vegetables like carrots, celery, and mushrooms for a quick, easy, and low calorie snack!" or the question "Did you buy fresh raw vegetables at the grocery store for snacks this week? (y/n)". If a participant responded to a text message that was a question, he or she would always get a response based on the answer provided. For the above question ("Did you buy fresh raw vegetables at the grocery store for snacks this week?"), if the participant responded "no," he or she would see the response "Be sure to add your favorite raw veggies like carrots, red peppers, and mushrooms to your shopping list."

Table 1. Representative weekly sequencing of SMS and MMS messages

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	Weight Graph	Weekly Topic Tip	Energy Balance (EB) Tip	Weekly Topic Question	Weekly Topic Tip	EB Question	Weekly Topic Tip
Evening	EB Question	Weekly Topic Question	EB Question	Weekly Topic Tip	Weekly Topic Question	EB Tip	Weekly Topic Question

The overall system consists of four components: (1) a Web-based application to enroll participants and set user preferences; (2) a database to store the participants' records, rules, and messages sent and received; (3) an application to determine the appropriate timing and message to send and to process the received replies; and (4) a text message delivery/reception platform. The system also had tools that enabled continuous technical monitoring to recognize anomalies such as messages and rules missing from the database, logic mistakes, or unexpected responses from participants, indicating that an individual may be having difficulties with the system. These tools alerted the case manager, who could contact the participant by phone or email to prevent user frustration and increase adherence and satisfaction.

A baseline dietary assessment [20] for each participant was used to identify unique diet behavior challenges that may contribute to increased caloric intake (eg, snacking behaviors, pacing of consumption, and self-monitoring of food intake). The server processed these data to create goals to target based upon particular logic rules of the expert system. These goals were then presented to the user via text or MMS messages to serve as prompts for food selection and behavioral improvements. At intervention onset, participants were given a printed binder with nutrition topics and behavioral strategies to supplement the phone-based messaging and a food and exercise journal to support self-monitoring. They also received brief (5-15 minute) monthly phone calls from a trained health counselor to encourage continued participation in the program and to work through any technical issues they might be having with the intervention. During the counseling calls, the health counselor followed a script designed to assess progress and barriers to weight loss. In addition, the health counselor would inquire about any of the following: weekly topics (Which topics are helpful? What have you learned? Is there any information missing?); text messages (Are they helpful?); current physical activity and eating plan (What is your current physical activity plan? How are you cutting calories?); social support (Have you been getting social support from the people around you?); or environment (Have you made any changes to your environment?). The health counselor would then provide feedback on what was discussed during the phone call and offer solutions to overcoming barriers.

Comparison Group

The usual care comparison group received the same baseline dietary assessment as the intervention group and was mailed one to two pages of print materials once a month for 4 months. The print materials differed from the binder received by the intervention group. Print materials included information and tips on nutrition and weight loss, walking basics, fruit and veggie basics, and how to make physical activity a habit. Some of the topics and content overlapped information provided in intervention group's binder and text messages. The comparison group did not receive telephone calls or text/MMS messages.

Study Design

Evaluation of the system was accomplished in a randomized controlled trial with participants randomized to either the intervention or usual care comparison group (Figure 1). Assessments were completed at baseline, 2 months, and 4 months. The study was approved by the Institutional Review Board at the University of California, San Diego, CA.

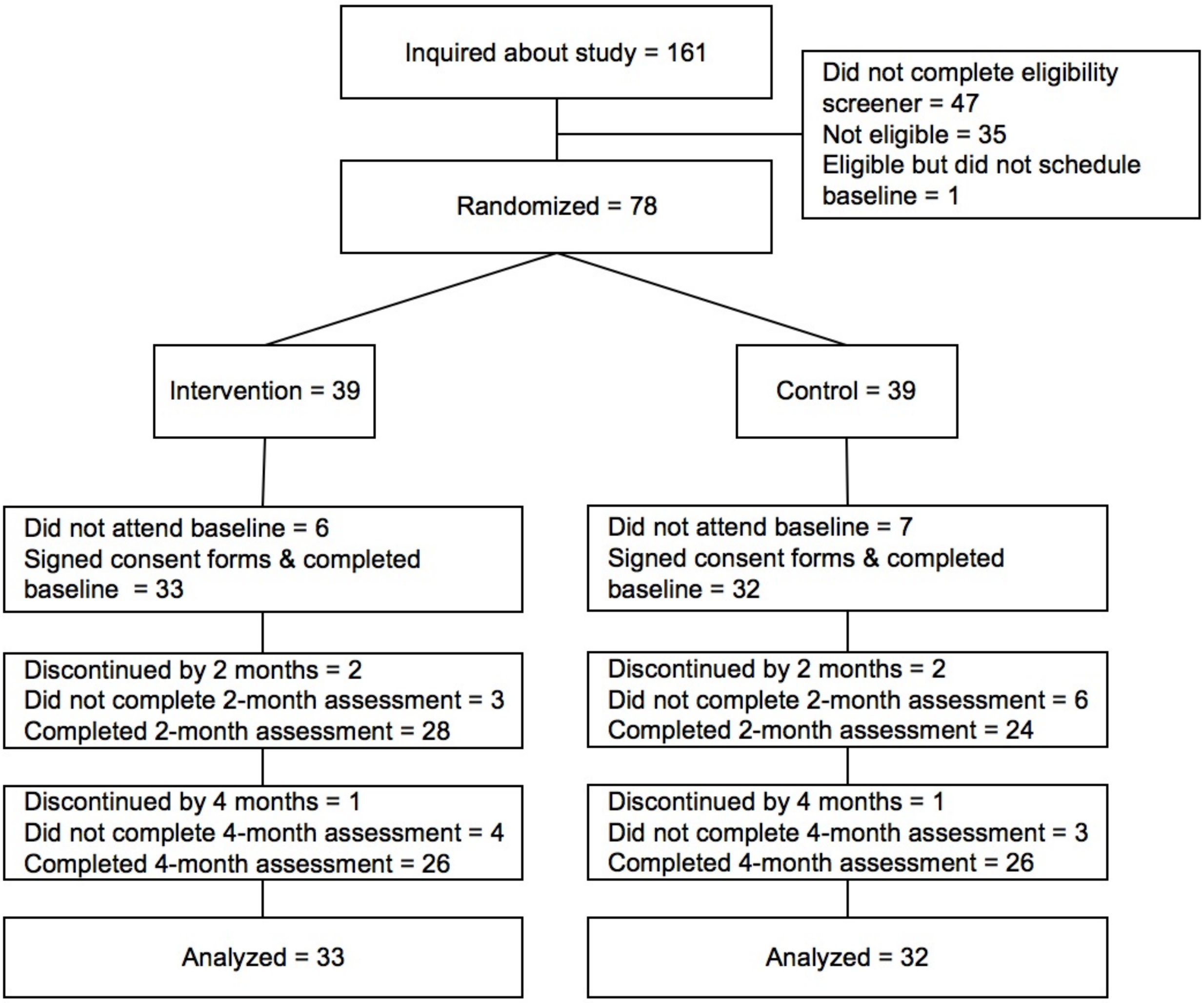
Measures

The primary outcome was weight in kilograms measured in the research offices using a calibrated scale.

Participants and Recruitment

Participants were recruited in 2007 from the community via newspaper ads, flyers, and announcements on craigslist. Interested individuals called the telephone number provided on the recruitment materials. Recruitment staff answered the telephone and screened potential participants for meeting the following inclusion criteria: 25 to 55 years old, overweight (BMI ≥ 25-39.9), not taking medications known to cause weight gain, and present use of a mobile phone for sending and receiving SMS messages or a willingness to learn. Individuals eligible and interested in the study were transferred to the study staff, who scheduled a baseline visit. During the scheduling process, individuals were assigned to either the comparison or intervention group by a computer-generated process using simple randomization. Participants were not informed of their group allocation status during this process. Following baseline measurements, neither study staff nor participants were blinded to participants' allocation. As no studies using SMS messages for weight control had been previously published, we did not have guidance on sample size for powering the study, so we based enrollment numbers on our best estimate of likely effects.

Figure 1. Flow diagram of participants



Statistical Analyses

Initial descriptive analyses examined sample characteristics, the randomization of participants, and distribution of variables. A mixed-model repeated-measures analysis compared the effect of the intervention group to the comparison group on weight status over the 4-month intervention period. The mixed-model analysis allowed for inclusion of all available data with missing values assumed missing at random. Model building methods outlined by Singer and Willett [21] were followed. An unconditional means model of baseline weight was evaluated first, followed systematically by models including a within-subject factor of time (0, baseline; 1, 2 months; 2, 4 months), a between-subjects factor of treatment group (1, intervention group; 0, comparison group), and the treatment by time interaction. Further models were planned to include sex, race (white versus non-white), ethnicity (Hispanic versus non-Hispanic), and age (mean centered). Neither race nor ethnicity independently influenced initial weight status or rate of weight change and were dropped from the models. A heterogeneous first-order autoregressive error covariance structure was specified for all models. Model fit was compared using the deviance statistic, the Akaike information criterion, and the Schwarz Bayesian criterion. Additionally, analysis of covariance (ANCOVA) models examined weight change between baseline and 4 months after adjusting for baseline weight, sex, and age. We handled missing for the ANCOVA analyses in two ways: (1) a completer analysis included participants with complete baseline and 4-month data only, and (2) an analysis using imputation (last observation carried forward [LOCF]) for participants missing 4-month data. All analyses were conducted using SPSS statistical software, version 12.0 (SPSS Inc, Chicago, IL, USA). All reported *P* values are for two-sided tests, with effects considered statistically significant at $P < .05$.

Results

A total of 65 participants (mean age 44.9 years, mean weight 89 kg, mean BMI 33.2 kg/m^2) completed baseline measures and were included in the analyses; 80% were women, 75% were white, and 17% were African American (Table 2). There were no differences in sample characteristics between the intervention and comparison groups, except for mean age—the intervention group was 5 years older ($P = .007$).

Table 2. Sample participant characteristics

Characteristic	Comparison (n = 32)	Intervention (n = 33)	Total (n = 65)	*P*
BMI, kg/m^2 (mean ± SD)	33.5 ± 4.5	32.8 ± 4.3	33.2 ± 4.4	.53
Sex female (%)	27 (84)	25 (76)	52 (80)	.39
Age, years (mean ± SD)	42.4 ± 7.5	47.4 ± 7.1	44.9 ± 7.7	.007
Hispanic (%)	10 (31)	6 (18)	16 (24.6)	.22
Race				.87
White (%)	24 (75)	25 (76)	49 (75)	
African American (%)	4 (13)	7 (21)	11 (17)	
Asian/Pacific Islander (%)	1 (3)	1 (3)	2 (3)	
Prefer not to state (%)	3 (9)	0 (0)	3 (5)	

Sample means for weight status over the course of the study are shown in Table 3. There were no significant differences in weight at baseline between the intervention and comparison groups. At baseline, the comparison group averaged 88 kg, and they did not lose weight between baseline and months 2 and 4. The intervention group averaged 90 kg at baseline and by months 2 and 4, weighed 86 kg and 85 kg, respectively.

Table 3. Unadjusted mean weights by groups

	Comparison			Intervention		
	n	Mean Weight (kg)	SD	n	Mean Weight (kg)	SD
Baseline	32	88.02	13.10	33	89.79	17.17
2 months	24	88.03	12.69	28	85.65	16.26
4 months	26	87.85	14.11	26	85.17	18.16

Table 4 shows the results of a mixed-model repeated-measures analysis that assumes any missing data were missing at random. No between-group difference was observed for the adjusted initial weight status. Differences for sex and age were found on adjusted initial weight status; males were 15 kg heavier than females, and age (mean centered) was negatively associated (−0.54 kg per year) with weight. At the end of 4 months, the intervention group lost more weight than the comparison (1.97 kg more; $P = .02$), after adjusting for time, sex, and mean age. The comparison participants' adjusted weight loss was 0.91 kg. Intervention participants' adjusted average weight loss was 2.88

kg. This equates to 1.01% and 3.16% weight loss in the comparison and intervention groups, respectively.

Table 4. Mixed-effects repeated-measures model parameter estimates for weight change

Primary Outcome Model[a]	Parameter Estimate	SE	*P*	95% CI	
Intercept	82.42	2.17	< .001	78.10	86.75
Group	1.09	3.04	.72	−4.98	7.17
Sex	15.12	3.48	< .001	8.17	22.06
Age	−0.53	0.20	.01	−0.92	−0.13
Time	−0.45	0.30	.13	−1.04	−0.14
Group × Time	−0.98	0.41	.02	−1.80	−0.17

[a] Group is coded as 0 for comparison and 1 for intervention; sex, 0 for female and 1 for male; time, 0 for baseline, 1 for 2 months, 2 for 4 months; age was mean centered.

Table 5 shows adjusted mean weight change for participants with complete data only and for participants where LOCF imputation substituted for missing data at 4 months. For both missing-data methods, the ANCOVA models revealed significantly greater weight loss for the intervention compared to the comparison group after adjusting for baseline weight, sex, and age. When examining participants with complete data, the intervention group lost 1.99 kg more than the comparison group (*P* = .04). The intervention group lost 1.70 kg more than the comparison group when missing values were imputed (*P* = .03).

Table 5. Adjusted weight change (kg) at 4 months using two missing-data methods, by group[a]

	Comparison					Intervention					*P*	Eta^2
	n	Mean	SE	95% CI		n	Mean	SE	95% CI			
Completers only	26	−0.47	0.64	−1.76	0.82	26	−2.46	0.64	−3.75	−1.18	.04	.09
LOCF imputation	32	−0.40	0.51	−1.43	0.63	33	−2.10	0.51	−3.11	−1.09	.03	.08

[a] ANCOVA models adjusted for baseline weight, sex, and age (mean centered). Completers includes participants with non-missing data at both baseline and 4 months only; LOCF, carrying the last observation forward to impute missing 4-month weight.

Adherence was calculated as the percentage of messages requesting a reply that prompted an actual response. During the first week, participants responded to all of the messages that requested a reply. By week 16, participants were responding to approximately two out of three messages. Overall, satisfaction with the intervention was extremely high, with 22 out of 24 (92%) participants stating that they would recommend the intervention to friends and family. Responses to an open-ended question about what users most liked included the following: “The messages served as an excellent reminder to watch what I ate.”; “I found texting my weight every week was extremely helpful.”; “Keeps me focused.”; and “I miss my 6AM message!”

Discussion

In this pilot study, we found that an intervention based primarily upon the use of tailored SMS messages was effective in promoting weight loss over 4 months among a group of overweight and obese adults. To our knowledge, this is the first randomized controlled trial to examine the use of daily SMS messages for this purpose. While the weight loss for the intervention group was modest (2.88 kg; 3.16%), the loss was robust when examined by different analyses and methods to handle missing data, and it may be meaningful, particularly at a population level. In the Diabetes Prevention Program, every 1 kg of weight loss was associated with a 13% reduction in the risk of incident diabetes [22]. These results compare favorably to an evaluation of eDiets.com, an Internet-based commercial weight loss program that was shown to produce a 0.9% loss of initial weight at 16 weeks [23]. They also compare favorably to the results found with the Internet-only treatment arm of a study comparing it to Internet plus behavioral e-counseling, where those randomized to the Internet-only arm lost, at 12 months, 2.2% of initial body weight, compared to 4.8% for the e-counseling group [24]. Finally, a study comparing mail, phone, and usual care for weight loss among overweight adults in a managed care setting found mean weight losses of 1.93 kg, 2.38 kg, and 1.47 kg at 6 months, respectively, results generally comparable to the findings in the current study [25].

While the intervention has several components (daily text messages, monthly paper materials, and brief phone calls), the cost of deployment was relatively low because the tailoring process is automated, both at program onset and with continued use. Thus, additional users can be added to such a system at a low cost per user.

There are several limitations to the study. Generalizability is limited because of the small sample size and relatively narrow age range of users. The 4-month period of study is short and insufficient to determine if a more clinically important threshold of 5% or 10% weight loss could be achieved. Because the intervention included other components to supplement the text messages, such as monthly print materials and brief monthly phone calls, the specific effects of the daily SMS system cannot be teased out and may limit population reach. However, our experience with brief phone calls and print materials suggests that these components are insufficient to produce the magnitude of weight change observed. Users were already familiar with using text messages and thus may have been of higher literacy and socioeconomic status than many who stand to benefit from weight loss programs. Inferences about whether participants habituate to text messages or whether the 3% weight change would persist over time also cannot be made from this study. On the other hand, the improvements in weight, combined with the favorable impression that the application made with almost all users, suggest the need to continue to explore the value of using daily text message–based interventions for weight control and weight-related behaviors.

There is promise for many health-related uses of mobile phones [26,27], and text messaging stands out since it is one of the only forms of communication that is usable on essentially all types of handsets and with all commercial phone companies. In addition, the popularity of this feature is growing among mobile users [28]. Thus, there are few barriers to the deployment of interventions using this relatively simple mode of communication to reach individuals with health behavior prompts and coaching.

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Conflicts of Interest

Dr. Patrick is co-owner of, and receives income from, Santech, Inc, which is developing products related to the research described in this paper. The terms of this arrangement has been reviewed and approved by the University of California, San Diego, in accordance with their respective conflict of interest policies. Drs. Griswold, Zabinski, and Norman and Mr. Raab have received consulting income from Santech.

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Abbreviations

BMI: body mass index
MMS: Multimedia Message Service
SMS: Short Message Service

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Original Paper

Integrating an eHealth Program for Pregnant Women in Midwifery Care: A Feasibility Study Among Midwives and Program Users

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Abstract

Background: Health messages may have the highest impact if they are given early in life. Therefore, the Dutch Ministry of Health identified pregnant women as a target population and initiated an innovative eHealth program to serve as a communication channel of health messages to pregnant women.

Objective: The aim was to study the feasibility of implementing this eHealth program into standard midwifery care and to investigate use and user perceptions of the online program among pregnant women.

Methods: All midwifery practices in Amsterdam affiliated with the Dutch Organization of Midwives (n = 25) were requested to implement the eHealth program within a pilot study from March to August 2006. Structured interviews were used to study feasibility of implementation among midwives. During the study period, 488 pregnant women registered themselves on the program website, after which monthly emails were sent to them. The emails were tailored to the stage of pregnancy and provided interactive questions plus answers on six topics and links to related websites. User statistics were registered until January 2007, and user perceptions were assessed with electronic questionnaires.

Results: In total, 80% (20/25) of midwifery practices implemented the program. These midwives gave a short oral explanation about the eHealth program to their clients (n = 1382; about 45% of the total number of clients during this period) and handed out an information brochure. After the pilot, 12 midwifery practices were willing to integrate the eHealth program into their standard care procedures. Regarding program usage, 84% (408/488) of the enrolled women accessed health information within the program. They opened 59% (1296/2213) of the quiz emails and accessed, on average, 16 topics (SD 11). Only 35% (143/408) of users used the hyperlinks to visit related websites. Most women perceived the eHealth information as easy to understand (96%; 157/163) and reliable (81%; 130/161), but only 39% (48/153) agreed that the information was available at the right time. Accessing more topics within the quiz emails was associated with a more positive perception of the program ($P = .02$), but the number of clicks to related websites was not associated with program perception ($P = .32$). The main improvement suggested by program users was to expand the information within the program.

Conclusions: It is feasible to integrate an innovative eHealth program in standard midwifery care, and about half of the practices would like to continue doing so. Program users accessed a substantial proportion of available health information; however, user perceptions were mixed. Therefore, this eHealth program may be a feasible communication channel to promote a healthy lifestyle to pregnant women after suggested revisions have been carried out.

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KEYWORDS

Internet; health promotion; pregnancy; midwife; implementation; user perception; process evaluation

Introduction

Most women welcome health-related information during their pregnancy and search for pregnancy-related information on the Internet [1-3]. The retrieved information is used, for example, for dietary and other lifestyle changes [4]. This offers an important opportunity to reach pregnant women with relevant health promotion messages that might influence the future health of their child and families. Therefore, the Dutch Ministry of Health initiated an innovative eHealth program to serve as a communication channel of health messages to pregnant women. This program aims to assist women in finding reliable information about a healthy pregnancy and provides links to websites with additional information.

In the Netherlands, 85% of pregnant women start their maternity care at a midwifery practice [5]. Midwives give information about a healthy lifestyle as part of standard care, but this lifestyle-related information is usually confined to the first appointment (at 8-10 weeks of pregnancy). Therefore, the eHealth program is designed to deliver information about a healthy lifestyle throughout the whole period of pregnancy. After enrollment, women receive monthly emails tailored to the stage of their pregnancy until their due date. Since information tailored to the stage of pregnancy is perceived as most useful by pregnant women [3], the eHealth program could be a valuable supplement to usual midwifery care.

We have performed a pilot study among almost 1400 pregnant women to study the feasibility of integrating the eHealth program into standard midwifery care. The process evaluation of this study is carried out in line with the RE-AIM model [6]. This model includes not only dimensions at the individual level but also dimensions that apply to the setting in which research is conducted in the evaluation of the potential public health impact of health promotion interventions. A better understanding of the barriers for implementation of the eHealth program perceived by midwives is of importance to improve the implementation and therefore to increase the public health impact. On the individual level, program usage data and user satisfaction will help to identify which aspects of the program could be improved to increase sustained program use. User satisfaction has been evaluated in previous studies of eHealth programs [7-11]. However, to our knowledge, this is the first study that incorporates factors related to the settings in which an eHealth program is to be implemented (the midwifery practices).

Therefore, the purposes of this paper are (1) to study the feasibility of implementing an online healthy lifestyle program into standard midwifery care, including midwife perceptions of the program, and (2) to analyze use and user perceptions of the eHealth program among pregnant women. The results of both objectives served to further improve the program before its countrywide implementation.

Methods

Description of the eHealth Program

The program consisted of monthly emails containing a link to a quiz, with a maximum of six questions, tailored to the stage of pregnancy. The quizzes were stored on a website. On the program website women could register for the program and find more information about it. However, health-related information was only accessible through the emails. The content of the intervention program was especially developed for women with a low education level, by presenting the information in plain language and short text blocks, thus requiring only basic literacy skills. Five health-promoting institutes were responsible for the content of the topic of their relative expertise (nutrition, exercise, lifestyle, smoking, or safety), and the Dutch Organization of Midwives was responsible for the content of the pregnancy topic. In this way, existing pregnancy-related information was brought together within one program.

Each email was personalized with the first name of the participant and the number of weeks she was pregnant, and it contained one question from the quiz. The participant was invited to click on the specified link to find out the answer to that question. Clicking on this link automatically opened a new screen with the quiz.

After opening the quiz screen, the six topics were displayed (Figure 1). Going over a topic with the mouse displayed the accompanying question. For example, the question at 16 weeks pregnancy about nutrition was “Should you eat more during pregnancy?” and the question at 36 weeks pregnancy about smoking was “Is it still useful to stop smoking?” After clicking on a topic/question, the participant was automatically transferred to the next screen in which the question was shown again together with two possible answers. Selecting an answer was followed by feedback. In this screen, the feedback was followed by a link to additional practical information. An example of practical information concerning lifestyle was “Do you like to drink wine during dinner? Try an alcohol-free wine sometime.” Additionally, hyperlinks to related websites (mainly of the health-promoting institutes) were provided after each topic, so participants could use them to search for additional information.

Figure 1. Screenshot of the quiz

Design of Pilot Study

In the Netherlands, midwives are independent paramedical practitioners, qualified to provide full maternity care to women whose pregnancy and childbirth are uncomplicated. The primary task of the Dutch midwife is to monitor the health status of pregnant women and their unborn children. Because of their frequent contacts throughout pregnancy and because of their expertise, midwives are considered to be important information providers for pregnant women, especially for women pregnant with their first child. Therefore, midwifery practices are a unique platform to inform pregnant women about the existence of an eHealth program with relevant and reliable pregnancy-related information. Furthermore, it is likely that information about the eHealth program could easily be incorporated into standard care since general health and lifestyle information is already given during the first midwifery visit.

All 25 midwifery practices in Amsterdam affiliated with the Dutch Organization of Midwives were requested to implement the eHealth program from March to August 2006. They were instructed to give oral information about the program and hand out an information brochure to all of their clients before the 16th week of pregnancy in order to motivate their clients to enroll in the eHealth program. The midwives informed 1382 women about the eHealth program, and 238 women (17%) subsequently registered themselves (at home) on the program website, as described in more detail elsewhere [12]. In addition, 250 women who heard of the program through other channels, such as friends or media, enrolled in the program. So, in total, there were 488 participants.

Feasibility of Implementation and Midwife Perceptions

In July 2006, the 25 midwifery practices were contacted by telephone to make an appointment for an interview. At this stage we checked if the practice had implemented the eHealth program. Practices that did not (actively) implement the program were asked a few short questions to discover why they did not participate. For the participating practices, a date was set for a structured interview. Preferably, the interview was conducted face-to-face within the midwifery practice with one or more midwives; when this was not possible, the interview was done by telephone. One midwifery practice was unavailable for the interview due to time restraints and personal circumstances of the midwives. However, the practice assistant gave a general impression of the implementation. The questions within the interview were categorized into four sections: implementation, program perception by midwives, points for improvement, and some general information about the midwifery practice. It took approximately 15-30 minutes to complete the interview. The answers of the midwives were summarized by the interviewer and manually recorded during the interview. To estimate the delivery rate of the program within the midwifery practices, the midwives were asked to record each client who was informed about the program on a specifically designed card. Furthermore, during the interview, the midwife gave an estimate of the number of clients visiting the practice.

Program Use

User statistics were registered until January 7, 2007, by a third party specialized in Internet technology (OOiP, The Netherlands) and included enrollment data, emails sent, quiz questions accessed, practical tips accessed, and related websites visited through hyperlinks within the program. A quiz email was considered as opened if at least one question was accessed. A self-completed questionnaire was used to assess participant characteristics at baseline.

User Perceptions

An online self-administered questionnaire was used to measure user satisfaction with the eHealth program. Invitations to complete the questionnaires were sent by email the week after the participants received the third quiz email, but no invitations were sent after the 40th week of pregnancy. The feedback questionnaire contained several statements about the program that could be rated on a five-point scale (“totally agree” to “totally disagree”). Participants could also indicate which of the six lifestyle topics they enjoyed most and found most useful, and overall satisfaction was rated with a score between 1 (“very bad”) and 10 (“very good”). The questionnaire ended with an open-ended question (“What could we do to improve the program?”). The participants who gave feedback were divided into three groups based on their scores on five user perceptions of the program: interest, usefulness, timing, pleasantness, attractiveness (see last five statements in Figure 2). Those who agreed with four or five statements were classified as having high satisfaction, with two or three statements as having intermediate satisfaction, and with zero or one statement as having low satisfaction.

Data Analyses

Upon enrollment, a unique personal identification number (ID) was assigned to each program user. The data from the baseline and feedback questionnaires were manually linked to an ID by means of name, zip code, and email address.

Descriptive analyses using means, standard deviations, medians, and percentages were used to describe program use and user attitudes. Chi-square tests were used to detect associations between participant characteristics and user attitudes. Analysis of variance (ANOVA) with follow-up trend analyses was used to detect associations between user satisfaction and program use. Furthermore, linear regression analyses were used to examine the association between five individual perception components (interest, usefulness, timing, pleasantness, attractiveness) and program use (dependent variable). SPSS version 12.0.1 (SPSS Inc, Chicago, IL) was used for all analyses, and statistical significance was set at a level of 0.05.

Results

Adoption Rate of Practices

In the pilot project, 80% (20/25) of midwifery practices informed their clients about the program. The other practices did not implement the program, mainly because they considered the program unsuitable for the majority of their clients (highly educated or non-Dutch-speaking women). One practice reported time constraints as the main reason.

Implementation

The midwives in the 20 participating practices informed their clients about the eHealth program during a standard visit. They all handed out an information brochure, and, with the exception of one midwifery practice, they all gave a short oral explanation about the eHealth program (Table 1). This was most often done during the client’s first visit to the midwife (8-10 weeks of pregnancy). Because this visit is usually used to provide lifestyle-related information, the information brochure was sometimes handed out together with other written materials. All midwives reported that the oral explanation only took a few minutes and that 98% (1354/1382) of women took the information home. Approximately 45% of all clients visiting the participating midwifery practices in the study period received information about the eHealth program. The midwives reported several reasons for not informing all their clients: they forgot (it takes time to integrate into routine care), they did not hand it out to clients without a computer, or the program was judged to be unsuitable for some of their clients (eg, highly educated clients or clients not proficient in Dutch).

Suggestions to facilitate further implementation of the program were to use more promotion materials and to reconsider the moment most appropriate for giving information about the eHealth program.

Attitudes of Midwives

About half of midwifery practices (12/25) wanted to integrate the eHealth program into their standard care after the end of the study period. Five practices that did not implement the program during the study period would also not implement it after the study period. The other eight practices would not like to continue implementation and had more negative program perceptions than midwives from practices with a positive intention to continue implementation (Table 1). The majority of midwives from practices with a negative intention judged the information within the program as too simple and of little added value to existing information sources. In general, the midwives of practices with a positive intention thought the program would have positive effects on the knowledge of pregnant women about a healthy pregnancy. They had a positive program perception, although some midwives had concerns about the simplicity of some quiz questions and missed having a function to search within all the available information.

Table 1. Practice characteristics, program implementation characteristics, and program perceptions of midwifery practices, stratified by the intention to integrate the eHealth program into standard midwifery care after the study period

	Not Implemented (n = 5)	Negative Intention (n = 8)	Positive Intention (n = 11)[a]
Midwifery Practice Characteristics			
Method of interview			
Face-to-face	0	4	7
Telephone	5	4	4
Estimated births in study period, mean (range)[b]	97 (25-170)	210 (150-335)	137 (20-195)
Client ethnicity[b]			
More Dutch than immigrants	2	5	5
Equal numbers of Dutch and immigrants	1	2	1
More immigrants than Dutch	1	1	4
Implementation Characteristics			
Information brochure handed out together with other information	N/A[c]	2	3
Short explanation of eHealth program	N/A	7	11
Program Perceptions			
Opinion on content	N/A		
Positive		0	6
Neutral		2	1
Negative		4	0
Has not seen content		2	4
Opinion on quiz format	N/A		
Positive		1	6
Neutral		4	5
Negative		3	0
Opinion about additive value	N/A		
Valuable		1	9
Not valuable		7	1
Don’t know		0	1
Perception of effectiveness on knowledge about a healthy pregnancy	N/A		
Effective		2	9
Not effective		3	0
Don’t know		3	2
Opinion about national implementation			
Positive	1	2	11
Neutral	2	2	0
Negative	2	4	0

[a] One practice was not available for interview, but the assistant indicated that the practice continued implementation after the pilot period.

[b] Data for one midwifery practice that did not implement the program are missing.

[c] N/A = not available or not applicable.

Program Use by Pregnant Women

During the study period, 488 pregnant women registered themselves on the program website, and 16% (80/488) of them enrolled but did not access any information available within the program; therefore, they are excluded from all further analysis. The baseline characteristics of participants are summarized in Table 2.

Table 2. Baseline characteristics of participants (n = 343)[a]

	%
Demographic	
Age (years), mean ± SD	30 ± 5
High level of education	66
Full-time job (≥ 32 hours per week)	56
Non-Dutch ethnicity	26
First-time pregnancy	65
Lifestyle	
Overweight before pregnancy (BMI ≥ 25)[b]	19
Smoking during pregnancy	
Yes	3
Until pregnancy was known	14
No	84
Alcohol use during pregnancy	17
No use of folic acid supplements	10
Internet	
Internet at home	96
Used internet > 1 hour per week	86
Used internet to find pregnancy-related information	87

[a] The total number of participants was 488; response rate for self-completed questionnaire at baseline was 70%.

[b] BMI (body mass index) = weight/height^2(kg/m^2)

Program users (n = 408) received a mean of 5.4 (SD 1.6) quiz emails and accessed an average of 3.2 (SD 1.8) of those quizzes during their pregnancy (Table 3). A minority (7%) received less than three quizzes because they enrolled in the program late in their pregnancy. Each quiz consisted of six questions (with the exception of the quiz at 16 weeks of pregnancy, which consisted of four questions). The mean number of quiz questions opened during pregnancy was 15.5 (SD 10.7). Thus, each participant accessed, on average, 16 different health promotion messages. The mean number of practical tips opened was 5.8 (SD 6.2). The participants clicked an average of 2.3 (SD 4.1) embedded links, although 65% (266/408) of participants did not click on any link to visit a related website. Of the participants who did visit a related website, 68% (97/142) visited several websites covering five or six different lifestyle topics. Overall, in terms of participation measures, 59% (1296/2213) of sent quiz emails were opened and, within those quizzes, 85% of questions were accessed, but practical tips (37%) and links to related websites were used less often (12%).

Table 3. Health-related information received and accessed by program users (n = 408)

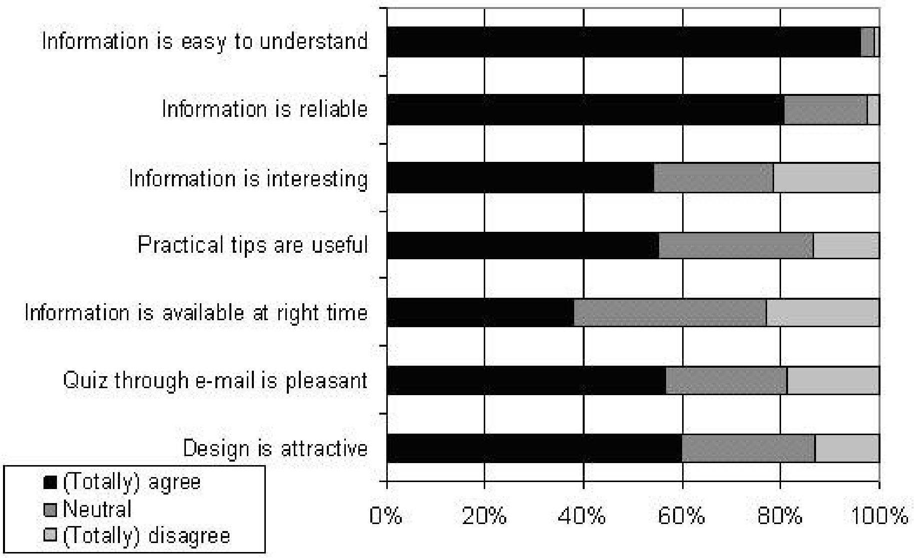
	n	%
Number of quizmails received		
1-2	29	7
3-5	142	35
6-7	237	58
Mean (SD), median	5.4 (1.6), 6	
Number of quizmails opened		
1-2	172	42
3-5	186	46
6-7	50	12
Mean (SD), median	3.2 (1.8), 3	
Number of opened quiz questions		
1-10	166	41
11-20	110	27
21-30	88	22
31-40	44	11
Mean (SD), median	15.5 (10.7), 13	
Number of opened practical tips		
None	65	16
1-8	242	59
9-16	75	18
17-33[a]	26	6
Mean (SD), median	5.8 (6.2), 4	
Number of clicks to related websites		
None	266	65
1-6	112	27
7-14	21	5
15-28	9	2
29-40	0	0
Mean (SD), median	2.3 (4.1), 0	
Number of different lifestyle topics visited through hyperlinks		
None	266	65
1-2	13	3
3-4	32	8
5-6	97	24
Mean (SD), median	1.7 (2.5), 0	

[a] The maximum number of available tips was 33 because not all questions included practical information.

User Perceptions

Not all participants received three quiz emails and therefore did not receive an invitation to complete the feedback questionnaire (n = 32). Taking this into account, the response rate for the feedback questionnaire was 43% (163/376). Most women evaluated the program as easy to understand (96%; 157/163) and reliable (81%; 130/161), although only 39% (61/161) agreed with the statement that the information was available at the right time (Figure 2). Overall, the average rating was 6.5 (SD 1.5, range 1-10). According to participants, the most useful subjects were pregnancy (31%; 48/153), nutrition (25%; 38/153), safety (23%; 35/153), and lifestyle (14%; 21/153). Almost half (75/152) of program users perceived pregnancy as the most interesting topic, followed by nutrition (20%; 30/152) and lifestyle (16%; 24/152). About half (87/163) of participants who completed the questionnaire also completed the open-ended feedback question. The most common (70%; 61/87) remarks were that they would like to receive more information, more in-depth information, or more variation of information, or they stated that the program gave them little new information.

Figure 2. User perceptions of the eHealth program (n = 163)



Program Use by User Perceptions

The participants who completed the feedback questionnaire were divided into three satisfaction groups based on their responses to the statements about the program (Table 4). The three groups did not differ in the number of quiz emails received ($P = .81$). A higher satisfaction with the program was associated with accessing more information within the program, although there was no significant association between satisfaction and the number of related websites visited ($P = .32$). There was no association between satisfaction and educational level ($P = .21$) or with any other personal characteristic shown in Table 2 (data not shown).

Table 4. Participation measures and program rating by user satisfaction

	Low Satisfaction (n = 49)	Intermediate Satisfaction (n = 54)	High Satisfaction (n = 60)	Linear Trend, *P*
Quiz emails received	5.9 ± 1.2	5.7 ± 1.3	5.9 ± 1.0	.81
Quiz emails opened	3.9 ± 1.5	4.2 ± 1.7	4.5 ± 1.4	.04
Quiz questions opened	19.3 ± 10.0	21.7 ± 9.9	23.5 ± 9.0	.02
Practical tips opened	6.5 ± 5.9	8.2 ± 7.0	9.7 ± 7.4	.02
Clicks to related websites	2.7 ± 4.4	2.9 ± 4.0	3.5 ± 4.9	.32
Overal program rating	5.2 ± 1.4	6.5 ± 1.0	7.6± 0.8	<.001

We used regression analyses to investigate the association between individual perception components and program use and found that higher perceived interest and usefulness were associated with accessing more questions ($\beta = -2.4$, $P = .01$; $\beta = -2.2$, $P = .04$, respectively) and tips ($\beta = -1.6$, $P = .02$; $\beta = -2.3$, $P = .002$, respectively). Women who found the program interesting or useful accessed about four more questions or tips than women who did not find the program interesting or useful. A higher perceived attractiveness of design was only associated with accessing more tips ($\beta = -2.3$, $P = .003$), with women who found the design most attractive opening about four more tips than women who did not find the design attractive. There were no associations between perception components and the number of emails opened or the number of related websites visited. When the five individual components were included simultaneously into one regression model, no significant associations with the number of questions opened were seen, while attractiveness of design was still associated with the opening of tips ($\beta = -1.7$, $P = .04$). Furthermore, all five components were associated with the overall rating.

Discussion

A unique feature of this study is that the feasibility of an eHealth program was studied among both health professionals who provide the program as well as program users. This pilot study shows that it is feasible to integrate an eHealth program into standard midwifery care. About half of the midwifery practices would like to continue implementation of the program. Program users accessed a substantial proportion of available health information, although user perceptions were mixed. Therefore, this eHealth program may be a feasible communication channel to provide reliable information about a healthy lifestyle to pregnant women.

Practical Implications

A high proportion (80%) of midwifery practices implemented the program. However, this adoption rate may not be achieved with the countrywide implementation. Some of the midwives were actively involved in the development of the program, and there were personal contacts with the publisher of the online program, which probably increased the adoption rate. However, the study implementation was done in a real-life setting and shows promise for the future countrywide implementation since half of the practices would like to integrate the program in their future standard care. Unwillingness to continue implementation of the program was not related to practical barriers, but to how midwives perceived the program. More practices may integrate the program into their future standard care if it was emphasized that the program is designed to bring existing information together and that this feature helps women to gather all relevant information easily, since several midwives had a negative perception of the program because it contained little information that was not already available from other sources.

The program users accessed, on average, 16 different health promotion messages during their pregnancy, which means that, in general, about half of the available health information was seen. Because user perceptions were mixed and several revisions were suggested, the program will be improved before the countrywide implementation, which may increase program usage.

It is thought that program satisfaction within the study is somewhat overestimated. The women who completed the feedback questionnaire accessed more topics ($P< .001$), tips ($P < .001$), and related websites ($P= .02$) than women who did not complete the questionnaire, and satisfaction was associated with more intensive use of the program. However, women who completed the questionnaire did not differ in baseline characteristics compared to women who did not complete the feedback questionnaire, with the exception of a more favorable smoking status among women who gave feedback. There was no association between education level and satisfaction with the program, although the program was designed specifically for women with a lower education. The frequent remark that the program hardly contained any new information was made by women with both a high and low education.

Our results showed that the perceived attractiveness of design was an important factor influencing program use.

Strengths and Limitations

A strength of our study is that we studied feasibility of the program among both users and midwives using a combination of quantitative and qualitative data. The user perceptions are supplemented with objective usage data, which provide further insight into the program features that need improvement. Furthermore, the evaluation among midwives indicated that the implementation of the program is feasible in a real-life situation.

In most midwifery practices several midwives work together. A limitation of the study is that the interviewed midwives might have had more positive attitudes toward the program than their non-interviewed colleagues. Therefore, we asked all midwives to register all clients to whom they gave information about the program. These data were used to estimate a more objective program delivery rate. The interviews gave insight into the reasons why midwives did not advocate integration of the program into standard care.

Some midwives expressed concerns about the reach and effectiveness of the program. Indeed, previous work showed that disadvantaged women were least easily reached by the health information available in the eHealth program [12], and whether this program positively influences the future health of the child and family remains to be studied.

Comparison With Prior Work

To our knowledge, only one other eHealth program that made use of emails to promote health behaviors has been evaluated previously [13]. This program was implemented among employees of a large health insurance company and delivered daily health tips during working days for 26 weeks with embedded links for self-monitoring tools and additional information. Their results showed that approximately 60% of participants opened four or five emails per week for most of the study period. This might imply that the emails to pregnant women could be sent much more frequently than once a month, which is in agreement with our finding that participants would like to receive more information. With regard to embedded links, it was found that approximately 90% of participating employees sought additional information at least once, which is much higher than the 35% in our study. This might simply be due to the higher number of available links in their program (> 250) compared to ours (40) or to other factors, such as a more stimulating description of the content of the related website (eg, “Learn new moves with these fitness videos” compared to “Would you like to know more? Have a look on [site address]”).

To our knowledge, there are no other studies that evaluate the feasibility of integrating an Internet program with health information within standard health care. One study introduced an eHealth program to general practitioners to support their patients with lifestyle changes. However, this study focused on practitioner views toward program usability and program design [14].

Conclusions

It seems feasible to integrate an eHealth program into standard midwifery care. About half of midwifery practices would like to continue recommending an eHealth program to their pregnant clients, and hardly any practical barriers to implementation were reported. Program users accessed a substantial proportion of available health information; however, user perceptions were mixed. Therefore, this eHealth program may be a feasible communication channel to promote a healthy lifestyle to pregnant women after suggested revisions have been carried out. Further research should evaluate email intervals, user needs, and attractiveness of embedded links to optimize transfer and uptake of information.

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Conflicts of Interest

None declared.

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Original Paper

Comparing Administration of Questionnaires via the Internet to Pen-and-Paper in Patients with Heart Failure: Randomized Controlled Trial

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Abstract

Background: The use of the Internet to administer questionnaires has many potential advantages over the use of pen-and-paper administration. Yet it is important to validate Internet administration, as most questionnaires were initially developed and validated for pen-and-paper delivery. While some have been validated for use over the Internet, these questionnaires have predominately been used amongst the healthy general population. To date, information is lacking on the validity of questionnaires administered over the Internet in patients with chronic diseases such as heart failure.

Objectives: To determine the validity of three heart failure questionnaires administered over the Internet compared to pen-and-paper administration in patients with heart failure.

Methods: We conducted a prospective randomized study using test-retest design comparing administration via the Internet to pen-and-paper administration for three heart failure questionnaires provided to patients recruited from a heart failure clinic in Toronto, Ontario, Canada: the Kansas City Cardiomyopathy Questionnaire (KCCQ), the Minnesota Living with Heart Failure Questionnaire (MLHFQ), and the Self-Care Heart Failure Index (SCHFI).

Results: Of the 58 subjects enrolled, 34 completed all three questionnaires. The mean difference and confidence intervals for the summary scores of the KCCQ, MLHFQ, and SCHFI were 1.2 (CI -1.5 to 4.0, scale from 0 to 100), 4.0 (CI -1.98 to 10.04, scale from 0 to 105), and 10.1 (CI 1.18 to 19.07, scale from 66.7 to 300), respectively.

Conclusions: Internet administration of the KCCQ appears to be equivalent to pen-and-paper administration. For the MLHFQ and SCHFI, we were unable to demonstrate equivalence. Further research is necessary to determine if the administration methods are equivalent for these instruments.

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KEYWORDS

Heart failure; Internet; questionnaires; validation

Introduction

Using the Internet as a means to help manage patients with heart failure may improve quality of life and reduce health care costs [1-5]. It is important to further evaluate Internet-based disease management, and its evaluation may be facilitated by using the Internet to administer questionnaires. Indeed, Internet questionnaire administration may have advantages over pen-and-paper administration including being easier for participants to complete, improving completeness of data, and eliminating data entry errors that occur with the transcription of paper questionnaires [6,7]. However, it is important to consider that most questionnaires have been developed and validated for pen-and-paper administration, and there may be important differences between pen-and-paper administration and Internet administration that can affect data quality [8]. Responses of Internet questionnaires may differ from pen-and-paper questionnaires due to issues such as a participant's computer anxiety or differences in display on a participant's computer [9]. Whether Internet administration provides similarly valid results as the traditional administration of questionnaires should not be assumed, and it has been recommended that each questionnaire be validated for Internet administration [7,10].

There is some data on the administration of questionnaires via the Internet compared to pen-and-paper administration. Overall, the data implies that Internet administration of questionnaires is associated with lower completion rates but less missing data compared to traditional administration of questionnaires [6]. There is also some evidence concerning whether Internet administration provides similar participant responses as pen-and-paper administration. They appear to be equivalent based on quality-of-life measures in adolescents, health-related questionnaires completed by Internet volunteers, and trauma survey in healthy college volunteers [11-13]. However, to date, there is little data on the equivalence of responses in patients with heart failure or other chronic complex medical conditions. Patients with heart failure differ from patients in previous survey samples by being older and by having more co-morbidities [14].

Since improving quality of life is recognized as one of the main goals of managing heart failure [15], validating questionnaires which assess this parameter is important. We hypothesized that Internet administration would provide similar results as pen-and-paper administration in a cohort of patients with heart failure. We tested this by evaluating equivalency using the test-retest study design of three heart failure questionnaires.

Methods

Study Design

This was a prospective trial comparing pen-and-paper administration to Internet administration using classic test-retest design. Between June 2006 and May 2007, we randomized participants to first complete either the pen-and-paper questionnaire or the Internet questionnaire. We then retested the participants two weeks later with the alternate method of administration. The interval of two weeks between retesting was considered short enough to minimize clinical change yet long enough to reduce recall bias.

Participants

We enrolled patients from the Heart Function Clinic at Toronto General Hospital, University Health Network, Toronto, Ontario, Canada. The Heart Function Clinic is a tertiary care, multidisciplinary heart failure clinic. Patients were eligible for inclusion in the study if they were diagnosed with heart failure, aged 18 years or older, able to access the Internet, able to read and comprehend English, and able to provide informed consent. Participants were given information describing the study at the time of their clinic appointment. For those people interested in participating, the research associate initiated the process of informed consent. Ethics approval was obtained from the research ethics board at the University Health Network. Since this trial did not have an intervention, it was not registered with a randomized trial registry.

Randomization and Allocation

A computer-generated randomized schedule was prepared by the study biostatistician and then stored and securely concealed until allocation was assigned. For those patients meeting the inclusion criteria and providing informed consent, the research assistant assigned the next randomization sequence according to the schedule. Patients were first allocated to either pen-and-paper or Internet administration. Neither blinding of participants nor the research assistant was possible due to the study design.

Data Collection

If the participant was randomized to the pen-and-paper version first, they either completed the questionnaires in the clinic or completed them at home and then returned them by mail. If they were initially randomized to the Internet version, they either completed them online at a computer in the clinic or at home. Two weeks later, participants were retested by the alternate method. After one week, email reminders were sent to any participants who had not completed either set of testing.

Instruments

We administered the following surveys, none of which had been previously validated for use on the Internet:

- Kansas City Cardiomyopathy Questionnaire (KCCQ) [16]. The KCCQ consists of 23 items measuring the impact of heart failure. Including the overall summary score, there are 10 summary scores measuring the dimensions of a patient's physical function, symptoms, social limitation, self-efficacy, and quality of life. The overall summary score ranges from 0 to 100 with higher scores representing better quality of life. The KCCQ has been validated, used in large randomized controlled trials, and found to be highly responsive [16-19]. A change of over 5 points on the KCCQ summary score is considered to be a clinically significant change in heart failure status [17].
- Minnesota Living with Heart Failure Questionnaire (MLHFQ) [20]. The MLHFQ is a questionnaire that provides a patient's self-assessment of how heart failure affects his or her daily life. It consists of 21 items, each

with the same 0 - 5 Likert scale. The range of scores is 0 - 105 with higher scores representing worse quality of life. Subscores include physical and emotional dimensions. The MLHFQ has been validated and is commonly used as a measure of health-related quality of life of heart failure patients in large randomized controlled trials [21-23]. The minimal clinically important difference is considered to be 5 - 7 points on the total score [24,25].

- Self-Care of Heart Failure Index (SCHFI) [26]. The SCHFI is a 15-item questionnaire measuring self-care. It consists of three subscales: management, maintenance, and self-confidence. The range of scores for each subscale is 16.7 - 100, 25 - 100, and 25 - 100, respectively, with higher scores representing more self-care. The range of the summary scale is 66.7 - 300. While it has been validated, the minimal clinically significant difference is not yet known [26].

Outcomes

Our primary outcome of interest was the difference in scores between Internet and pen-and-paper administration of the main summary scores for each of the three instruments. Outcomes of secondary interest were the differences in the subscores of the three questionnaires and also whether the order of administration affected participants’ responses.

Sample Size

As the KCCQ has been found to be more responsive than the MLHFQ [16], this instrument was used to calculate the sample size. In the original validation of the KCCQ, the authors performed a test-retest validation of the KCCQ over a 3-month period [16]. Over the 3-month period, the mean clinical summary score changed by -2.1 in “stable patients” with a *P*-value of .36. This equated to a standard deviation of 14.2. Assuming that half of the variance observed was true change and half was due to measurement error, the standard deviation of change scores due to measurement error would be 10.01. We assumed that any change in the KCCQ over 5 was significant. Using an alpha error of .05 and beta error of .20, we calculated the desired sample size for an equivalence study to be 35 subjects per group and then assumed two groups, resulting in a total of 70 subjects. In retrospect, this calculation likely overestimated our desired sample size, since the analysis was based on paired differences of a single group [27]. Thus, the true sample size required was 35 subjects. Due to slower than expected enrollment, the study was terminated at one year, before the planned enrollment of all 70 subjects was completed.

Analysis

Mean paired differences between delivery methods were calculated for the summary scores and subscores for each of the three questionnaires. To determine whether the Internet and pen-and-paper administration methods were equivalent, we calculated one-sided confidence intervals. Since a statistical test for an equivalence hypothesis is statistically equivalent to a pair of one-sided hypothesis tests, one-sided confidence intervals were reported as they can be more informative than *P*-values. Given that an acceptable equivalence margin is not precisely known for most of the scales considered, the confidence interval approach provides more detailed information concerning how close the results are between administration methods [28,29]. If one-sided confidence intervals were less than the minimal clinically important difference, the administration methods were considered equivalent for the KCCQ and MLHFQ. Since the minimal clinically important difference was not known for the SCHFI, the mean paired difference and one-sided confidence intervals were calculated to provide information about equivalence.

To determine whether order of administration affected responses, we performed a *t* test on the paired summary scores and sub-scores.

Results

From the start of the study in June 2006 until its completion in May 2007, there were a total of 58 participants enrolled. Of these participants, 28 received the paper version first and 30 received the Internet version first (Figure 1). The average age was 51, ranging from 24 to 80 years (Table 1).

Figure 1. Flow of study participants

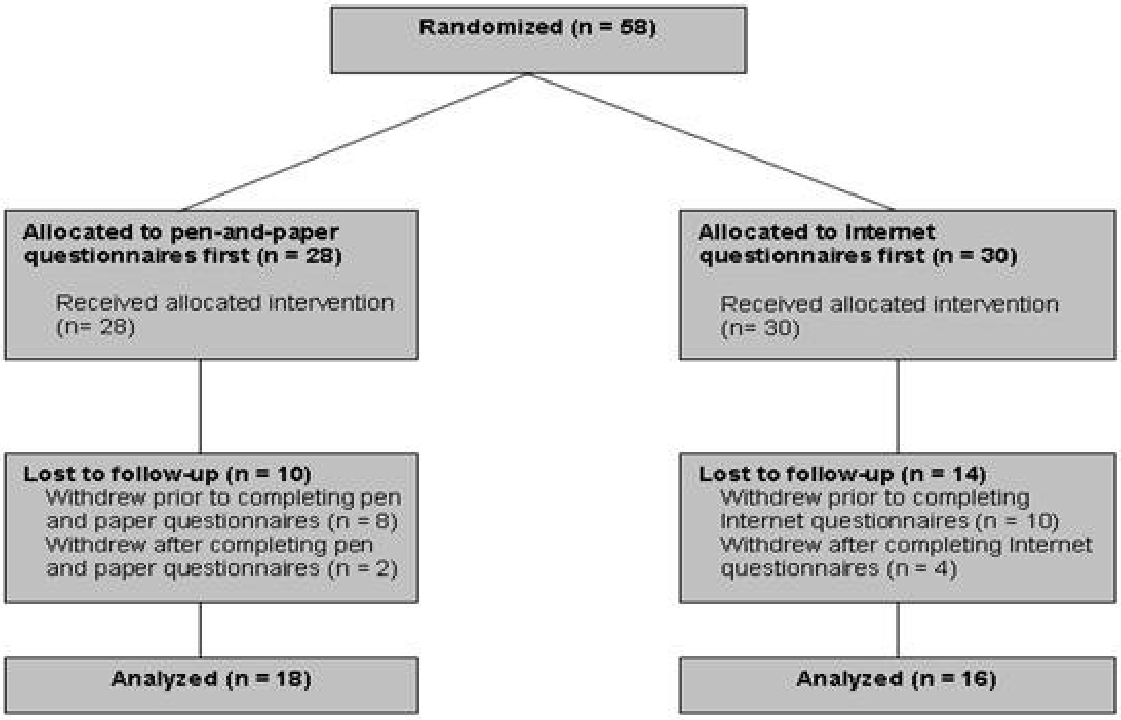

Table 1. Demographics of participants

	Paper First	Internet First	Completed Both	Total
n	28	30	34	58
Age in Years (SD)	50 (13.3)	52 (15.1)	49 (14.2)	51 (14.2)
Female	7 (25%)	12 (40%)	11 (32%)	19 (33%)
Highest education achieved				
Some High School	0 (0%)	0 (0%)	0 (0%)	0 (0%)
High School Graduate	7 (25%)	5 (17%)	7 (21%)	12 (21%)
Some University/College	4 (14%)	4 (13%)	6 (18%)	8 (14%)
University/College Graduate	14 (50%)	19 (63%)	19 (56%)	33 (57%)
Post-graduate	1 (4%)	1 (3%)	1 (3%)	2 (3%)
Undetermined	2 (7%)	1 (3%)	1 (3%)	3 (5%)

There were 34 participants who completed both Internet and pen-and-paper questionnaires. Of these 34 subjects, 18 completed paper questionnaires first, and 16 completed Internet questionnaires first. There were 4 participants who completed Internet questionnaires but did not complete pen-and-paper questionnaires. Conversely, 2 completed pen-and-paper questionnaires but did not complete Internet questionnaires.

The summary scores and subscores for the KCCQ, MLHFQ, and SCHFI are shown in Table 2. For the KCCQ, the one-sided confidence limits of both overall and clinical summary scores were within the equivalence margin of 5, demonstrating that the Internet and pen-and-paper versions are equivalent; for the MLHFQ, the one-sided 95% confidence intervals were larger than the minimally clinical important difference of 5 - 7; and for the SCHFI, there were wide ranges in the one-sided confidence intervals.

Table 2. Paired differences and one-sided confidence intervals for the overall and sub-domain scores for the three questionnaires

	Internet			Paper			Difference			95% One-sided CIs	
	n	Mean Score	SD	n	Mean Score	SD	n	Mean Paired Score	SD	Lower	Upper
KCCQ											
Overall Summary Score	38	71.8	19.9	36	70.1	22.0	34	1.2	9.5	-1.5	4.0
Clinical Summary Score	38	78.0	18.3	36	77.9	19.1	34	-0.1	13.7	-4.1	3.8
Physical Limitation[a]	37	75.5	23.4	36	75.7	22.6	33	-0.76	21.8	-7.19	5.68
Symptom Stability	38	54.6	16.3	36	55.6	19.0	34	-0.74	17.9	-5.94	4.47
Symptom Frequency	38	79.8	19.4	36	78.2	20.9	34	1.96	13.3	-1.91	5.83
Symptom Burden	38	80.9	19.4	36	81.9	18.4	34	-1.47	13.1	-5.26	2.32
Total Symptom Score	38	80.4	18.3	36	80.1	19.0	34	0.25	12.0	-3.23	3.72
Self-Efficacy	38	83.9	17.4	36	82.3	21.6	34	1.10	15.8	-3.48	5.69
QoL	38	63.8	23.7	36	60.2	27.1	34	2.45	13.1	-1.34	6.24
Social Limitation[a]	37	66.1	27.2	36	64.3	29.9	33	2.21	13.1	-1.66	6.08
MLHFQ											
Overall	38	39.3	25.6	36	36.4	26.3	34	4.0	20.70	-1.98	10.04
Physical	38	18.5	11.8	36	15.3	11.5	34	3.8	8.65	1.28	6.31
Emotional	38	7.1	6.0	36	8.1	6.5	34	-0.88	5.98	-2.62	0.85
SCHFI											
Overall	36	224.2	34.9	34	215.7	31.5	31	10.1	29.4	1.18	19.1
Maintenance	38	73.4	11.6	36	71.0	12.4	34	2.8	8.3	0.39	5.20
Management[a]	37	78.0	18.6	34	73.3	16.6	31	5.7	19.2	-0.21	11.5
Confidence[a]	36	71.4	17.4	35	71.3	18.0	32	1.4	15.6	-3.31	6.05

[a] Note that sample size for some subscores is less than total sample size due to different responses, not due to missing data.

With respect to order of administration, Table 3 summarizes the difference between Internet and pen-and-paper administration for the three questionnaires. The *P*-values were not adjusted for multiple testing. We observed no difference due to the order of administration.

Table 3. Effect of order of administration on mean paired differences for the three questionnaires

	Paper First			Internet First			*P* value
	n	Mean Score	SD	n	Mean Score	SD	
KCCQ							
Overall Summary Score	18	4.0	9.1	16	-2.0	9.2	.07
Clinical Summary Score	18	2.9	12.5	16	-3.5	14.5	.18
MLHFQ							
Overall	18	0.9	14.0	16	7.5	26.4	.38
Physical	18	3.3	6.3	16	4.3	10.9	.76
Emotional	18	-2.2	5.5	16	0.6	6.3	.17
SCHFI							
Overall	17[a]	15.8	30.9	14	3.3	26.8	.24
Maintenance	18	3.3	8.0	16	2.2	8.8	.69
Management	17 [a]	7.1	17.2	14	3.9	21.9	.66
Confidence	18	4.9	19.0	14	-3.1	8.4	.12

[a] Note that sample size for some subscores is less than total sample size due to different responses, not due to missing data.

To determine whether there was a true clinical change over the test-retest interval, we examined the responses to the symptom stability question from the KCCQ: “Compared with 2 weeks ago, have your symptoms of heart failure (shortness of breath, fatigue or ankle swelling) changed?”. Of the respondents, 79% reported no change or no symptoms (n = 27), 15% reported slight changes (n = 5), and 6% (n = 2) reported their symptoms were much better.

Discussion

Principal Results

In patients with heart failure, we found that Internet administration was equivalent to pen-and-paper administration for the Kansas City Cardiomyopathy Questionnaire, a questionnaire that is known to be valid and responsive, as well as an independent predictor of poor prognosis [18,19,30].

We were unable to show that Internet administration was equivalent to pen-and-paper administration for the Minnesota Living with Heart Failure Questionnaire and the Self-Care of Heart Failure Index. The MLHFQ was not originally intended to be self-administered; rather, the intention was that research personnel would administer it. This may have affected both pen-and-paper and Internet responses. Indeed, it has been found that who administers the questionnaires (ie, whether self-administered or administered via interview) may have greater effects than how it is administered [8]. While the SCHFI had a larger absolute mean difference and greater confidence intervals than both the MLHFQ and KCCQ, this is likely attributable mostly to the greater range of the summary scale. For the SCHFI, further research to establish the minimal clinically important difference would help to determine if delivery methods are indeed equivalent.

Limitations

There were several study limitations of note. Firstly, enrollment was slow and, after one year of recruitment, we did not achieve our desired sample size. While our sample size was much smaller than previous validation studies, this may be due to the fact we studied people with a chronic disease as opposed to people from the healthy population [11-13]. In any case, due to an overestimation of our sample size, we achieved sufficient power to show equivalence for the KCCQ. Secondly, Internet access was a requirement which may have created a biased selection of those who were highly educated and relatively young. Indeed, the average age of our sample was 51 years, much younger than the 72 years which is the average age of patients admitted to our hospital with heart failure [31]. With respect to the level of education, 60% of those enrolled had completed a university or college degree, compared to the 52% possessing the same level of education in the general population of our province [32]. Thirdly, survey completion rate was an issue. Of all who consented and were enrolled in the study, only 58% completed all parts. However, this is similar to other studies comparing pen-and-paper to Internet administration [33]. Finally, we examined three questionnaires but did not randomize the order of the three questionnaires. While our design is similar to other evaluations of Internet questionnaires [13,33], bias may have been introduced because questionnaires that were administered last may be less valid due to participant fatigue. Fatigue increases the chance that participants will provide an answer which is not accurate and may result in a difference in test-retest scores. The order of the questionnaires was as follows: KCCQ, SCHFI, and MLHFQ for paper questionnaires and SCHFI, MLHFQ, and KCCQ for Internet questionnaires. As a result of the order applied, fatigue effects would be least for the SCHFI, moderate for the KCCQ, and most for the MLHFQ. We are reassured by the fact that the KCCQ was still found to be equivalent despite any bias from fatigue.

Comparison With Prior Work

Previous literature suggests that pen-and-paper administration of questionnaires is equivalent to Internet administration [12,13,33]. To date, these studies have been limited to healthy, younger populations. This study adds to the literature, demonstrating the equivalence between pen-and-paper administration and Internet administration for the KCCQ in patients with heart failure.

Summary

In summary, Internet administration of the KCCQ appears to be equivalent to pen-and-paper administration. For the MLHFQ and SCHFI, we were unable to demonstrate equivalence, and further research is necessary to determine if the administration methods are equivalent for these instruments.

Our research suggests that one cannot presume equivalency between results from the same questionnaire administered over the Internet and by the pen-and-paper method in individuals with chronic disease. Therefore, it is important that such questionnaires are validated before being used online. Future research should confirm these findings and examine why such differences exist.

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Conflicts of Interest

None declared.

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Abbreviations

KCCQ: Kansas City Cardiomyopathy Questionnaire
MLHFQ: Minnesota Living with Heart Failure Questionnaire
SCHFI: Self-Care of Heart Failure Index

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Original Paper

The Use of Electronic Data Capture Tools in Clinical Trials: Web-Survey of 259 Canadian Trials

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Abstract

Background: Electronic data capture (EDC) tools provide automated support for data collection, reporting, query resolution, randomization, and validation, among other features, for clinical trials. There is a trend toward greater adoption of EDC tools in clinical trials, but there is also uncertainty about how many trials are actually using this technology in practice. A systematic review of EDC adoption surveys conducted up to 2007 concluded that only 20% of trials are using EDC systems, but previous surveys had weaknesses.

Objectives: Our primary objective was to estimate the proportion of phase II/III/IV Canadian clinical trials that used an EDC system in 2006 and 2007. The secondary objectives were to investigate the factors that can have an impact on adoption and to develop a scale to assess the extent of sophistication of EDC systems.

Methods: We conducted a Web survey to estimate the proportion of trials that were using an EDC system. The survey was sent to the Canadian site coordinators for 331 trials. We also developed and validated a scale using Guttman scaling to assess the extent of sophistication of EDC systems. Trials using EDC were compared by the level of sophistication of their systems.

Results: We had a 78.2% response rate (259/331) for the survey. It is estimated that 41% (95% CI 37.5%-44%) of clinical trials were using an EDC system. Trials funded by academic institutions, government, and foundations were less likely to use an EDC system compared to those sponsored by industry. Also, larger trials tended to be more likely to adopt EDC. The EDC sophistication scale had six levels and a coefficient of reproducibility of 0.901 ($P < .001$) and a coefficient of scalability of 0.79. There was no difference in sophistication based on the funding source, but pediatric trials were likely to use a more sophisticated EDC system.

Conclusion: The adoption of EDC systems in clinical trials in Canada is higher than the literature indicated: a large proportion of clinical trials in Canada use some form of automated data capture system. To inform future adoption, research should gather stronger evidence on the costs and benefits of using different EDC systems.

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KEYWORDS
Clinical trials; diffusion of innovation; electronic data capture; data collection

Introduction

Electronic data capture (EDC) systems are used in all phases of clinical trials to collect, manage, and report clinical and laboratory data [1]. The capabilities of those systems vary from the basic stand-alone database used for data entry in a single-site trial, to the more sophisticated systems supporting multisite international trials with remote data entry over the Web, data validation at the time of entry (eg, checking for out-of-range values or impossible combinations of values), real-time status reporting overall and per site, participant status tracking, and on-demand subject randomization.

Such systems have been discussed in the literature for more than a decade [2,3]. There are a handful of studies suggesting that the use of EDC systems can accelerate clinical trial start-up, reduce the overall duration of a trial, and reduce data errors [4-6]. To the extent that these positive results can be generalized, they make the case for wider adoption of this technology in clinical trials.

The number of published trials that use an EDC system has been rising [7], and there have been claims of a rapid uptake of this technology in clinical trials [8,9]. However, this optimistic assessment is inconsistent with reports that the failure rate of EDC adoption is as high as 70% [10], and, notwithstanding methodological weakness in the existing evidence, only 20% of trials are using EDC systems (see the systematic review in Multimedia Appendix 1). If indeed the failure rate is so high and the adoption rate is somewhat low, then either the technology is not quite ready for use or there are extreme difficulties being experienced in changing the practice of clinical trials to accommodate more automation. Should that be the case, then future research should investigate the quality and sophistication of EDC solutions and address the change management issues in the adoption of such a new technology in clinical trials workflows.

The primary objective of this study was to estimate the proportion of phase II/III/IV Canadian clinical trials that used an EDC system in 2006 and 2007. The secondary objective was to investigate three factors that can have an impact on adoption: trial size, source of funding, and type of participants.

Trial size was measured in terms of the target number of patients recruited and number of sites. We expected that larger trials would be more likely to use an EDC system. The total cost of a trial is partially driven by the number of patients recruited. Therefore, if a technology reduces the effort spent per patient (eg, on date entry and query resolution), then larger trials will likely benefit more from EDC technology than smaller trials, making it more likely that EDC would be adopted in the larger trials.

Source of funding indicated whether the trial was commercially or academically/foundation funded. Controlling for size differences, we expected commercially sponsored trials to be more likely to use an EDC system. A main reason is that academic/foundation trials are less likely to have the funding to license and implement an enterprise-level computerized system.

Type of participant indicates whether the participants were adult or pediatric. We had no a priori expectations about the direction of impact of this factor and included it for exploratory purposes.

The contributions of this work are as follows: (1) We have developed a scale to assess whether an EDC system is being used and determine its level of sophistication, (2) We have performed a content validation and unidimensional (Guttman) scaling of the EDC sophistication scale, (3) We provided an updated estimate of EDC adoption in Canadian clinical trials, and (4) We have identified which trial factors have an impact on EDC adoption.

Methods

Measurement

Definition of an EDC System

Previous studies of EDC adoption did not have a clear definition of what precisely an EDC system is (see the review in Multimedia Appendix 1). This increases the risk of variation among survey respondents' interpretation of the meaning of an EDC system and consequently increases the potential for error in the survey results.

The use of an EDC system in a clinical trial does not preclude the parallel use of paper case report forms (CRFs). Because of uncertainty about whether regulatory authorities will accept electronic documents as source documents (e-source), many sites still maintain source documents on paper [11-13]. With an EDC system in use, these data are typed into an electronic system by the site personnel for submission to the central database. There are also studies where data are being collected from/by different types of individuals using multiple modes of data entry. For example, nurses may enter data into an electronic system, but patient diaries are on paper, or vice versa. Therefore, in practice, paper and electronic systems coexist at the trial sites.

To ensure consistent interpretation of what an EDC system is in our study, we asked questions about the features of the systems that were used in the clinical trial. If an electronic system was used for data capture and management and it had at least a minimum set of features, then it was considered to be an EDC system. We define a minimum set of features as allowing trial sites to submit data electronically into the central database and to be able to query that central database for reports and aggregate statistics.

All trials have to enter/transfer their data at some point into an electronic database or file for analysis. If trial sites send paper CRFs or fax them to a central coordinating site and the on-paper data are transcribed into a central database, that database would not be considered an EDC system by our definition because data are not submitted electronically.

The feature set we used was obtained from comparative product reviews [7,14] and Food and Drug Administration (FDA) regulations, namely the FDA's 21 CFR Part 11 regulation "Electronic Records; Electronic Signatures" [15-19], which regulates the use of EDC in trials. A content validation study was performed to ensure that we had adequate coverage of critical EDC system features that are used in practice. The questionnaire development process, pilot testing, and the final questionnaire are provided in Multimedia Appendix 2.

The EDC Sophistication Scale

We can divide EDC systems into those offering "basic" and those offering "advanced" features. Thus, it is natural to have variation in the features that are implemented in different EDC systems. The more features that an EDC system implements, the more "advanced" it is considered.

If an EDC system implements the “advanced” features, then it would by definition also implement the “basic” features as well. The former would include the latter. This type of cumulative relationship can be modeled through a Guttman scalogram [20,21].

The original intention of Guttman scaling was that such a scale would measure a single underlying dimension of a phenomenon (eg, job satisfaction or symptoms of fear during battle [22]). The basic thesis of Guttman scaling is that it is possible to determine which items were endorsed by a subject from the knowledge of their total score (ie, an unweighted sum of their responses). Assume that we have a five-item scale. Then, in a Guttman scale, all subjects who endorse four items do so with respect to the *same* four items; those who endorse three items do so with respect to the *same* three items. Furthermore, these three items are among the four items endorsed by those who endorse four items.

Previous applications of the Guttman scaling approach include the study of the evolution, progression, or growth of various objects. For example, anthropologists utilize scalogram techniques for studying the evolution of cultures [23], and sociologists, in the study of the evolution of legal institutions [24].

The Guttman scale is suitable for defining cumulative functionality levels for an EDC system such that if a system implements, say, feature 5, then it is likely to have also implemented features 1, 2, 3, and 4. If features can be ordered, then the higher features signify more EDC sophistication.

We therefore used Guttman scalogram analysis to create an ordered scale of EDC sophistication, with lower scores indicating an EDC system that is more basic with fewer features, and higher scores indicating an EDC system that is more advanced. The coefficient of reproducibility [25,26] and the coefficient of scalability [27] are used to evaluate how well the data fit the cumulative scale. Common acceptable thresholds for these two indices are 0.9 for reproducibility and 0.6 for scalability [28].

Sampling Frame

Clinical trials with Canadian sites were identified through two main international clinical trials registries: ClinicalTrials.gov and Current Controlled Trials. Such registries have been used in the past to perform descriptive analysis, such as on the global growth of clinical trials [29]. Not all of the entries in these registries are, strictly speaking, controlled trials since they include phase IV observational studies as well.

Since the 1997 FDA Modernization Act, FDA-regulated efficacy drug trials for serious or life-threatening diseases or conditions have to be registered with ClinicalTrials.gov [30]. One analysis conducted in 2003 noted that there were more than 2000 investigational new drugs and 731 nongovernment-sponsored trials registered (around 37% registration rate) [31]. The 2007 FDA Amendments Act considerably expanded the scope of trials to be registered by including all trials except phase I and imposed penalties for noncompliance. Following the registration requirement by the major medical journals, led by the International Committee of Medical Journal Editors in 2005 [32,33], registrations with ClinicalTrials.gov have increased dramatically [34]. We therefore expected that ClinicalTrials.gov would have good coverage of commercial clinical trials, including those with Canadian sponsors as well as non-Canadian sponsors with sites in Canada.

The Canadian Institutes of Health Research (CIHR), which is the main public funding agency for health research in Canada, has a requirement that the randomized controlled trials it funds be registered with an International Standard Randomised Controlled Trial Number (ISRCTN) and that basic information about each trial be posted on the ISRCTN registry (Current Controlled Trials) [35]. We therefore expected that between the ISRCTN registry and ClinicalTrials.gov, most of the Canadian non-commercial trials would be captured.

Our sampling frame consists of registered trials that were running in Canada from January 1, 2006, to December 31, 2007 inclusive. This means trials were included that were started or terminated during that period, as well as ongoing trials that started before 2006 and those that were still running at the end of 2007.

Sample Size

Based on our systematic review (see Multimedia Appendix 1), we expected that 20% of all trials would be using an EDC system. For an estimate of the proportion of trials using EDC with a 95% confidence interval ± 5%, we would need 246 observations. It is reasonable to expect a 40% unit response rate for a Web-based survey [36,37]. Therefore, we needed to survey at least 615 clinical trials.

To analyze the factors affecting adoption, we constructed a logistic regression model [38] with a binary outcome (EDC adoption) of the form $Adoption \sim Type\ F + Type\ P + \log(Size)$, where *Type F* was a dummy variable indicating whether the trial was academic or industry, *Type P* was a dummy variable indicating whether the trial participants were adult or pediatric, and *Size* was the target patient recruitment.

Funding source and size were available/discernable from the two trial registries. We performed a log transformation on the target patient recruitment variable to ameliorate the heavy tail (the transformed variable does not deviate from normality according to the Kolmogorov-Smirnov test).

For the impact of size and whether a trial was academic or industry, our initial hypotheses in the introduction were directional. Therefore, we used one-tailed tests on the parameters for these two variables in our logistic model. For the adult versus pediatric impact on adoption, our initial hypothesis was nondirectional. Therefore, we adopted a two-tailed test for that analysis.

At 80% power and a baseline adoption probability of 0.2, a 246 sample size for the multivariate logistic regression model can detect an odds ratio (OR) of 1.57 at a one-tailed alpha level of 0.05 for a one standard deviation increase in the log target recruitment variable [39], which represents a plausible increase in the probability of adoption. Similarly, the OR for the binary academic/industry detectable at the same sample size is 2.26 for a change from academia to industry for a one-tailed alpha level of 0.05, and 3.7 for pediatric to adult for a two-tailed alpha level of 0.05. Therefore, the impact of type of participant would have to be quite large to be detectable.

Approach

The commercial SurveyMonkey system was used to run and manage the survey.

It has been noted that contact information in online clinical trials registries has created a burden on principal investigators (PIs) through excessive emails from patients, other clinicians, and direct marketers [40,41]. Therefore, we expected that most PIs who are the main contacts in these registries would be unlikely to respond to the survey themselves. Keeping that in mind, and considering that coordinators are the end users of an EDC system and would have the operational experience of an EDC if it was used in a trial, and that they would be more likely to respond to the questionnaire, we decided to survey Canadian site coordinators.

The registries did not always provide detailed contact information for the site coordinators. In such cases, we had to determine the contact information for the Canadian site coordinators ourselves. Two approaches were followed. Initially, an email was sent to the main contact of the clinical trial listed with ClinicalTrials.gov or Current Controlled Trials asking him or her to send us the contact information for the Canadian sites. If the above did not work (eg, often trials do not have contact information if the trial has stopped recruiting, the trial may provide a generic sponsor address as a contact, or a PI contact may not respond), we contacted the administrative person responsible for clinical research at the sponsor or for the Canadian sites listed in the registries asking for assistance in locating the coordinator.

Administration

Each study coordinator was contacted by email inviting him or her to participate in the survey. Three reminders were sent out at one-week intervals. Respondents were also entered into a raffle for three iPod Shuffles. A summary of the Web survey details according to the CHERRIES guidelines [42] is provided in Multimedia Appendix 3.

Analysis

The adoption rates are presented descriptively as a proportion with 95% confidence intervals [43].

The overall logistic regression model significance test is performed using the G statistic [38], and goodness of fit is evaluated using the Nagelkerke pseudo-R^2 [44,45]. This pseudo-R^2 tends to have low values compared to what one would expect in ordinary least squares regression models. Collinearity among the independent variables was assessed using the condition number [46,47]. In general, a condition number above 30 is considered problematic. Influential observations were detected using the delta-beta coefficient [48] and investigated.

Results

Description of Trials

In total, there were 947 registered trials with sites in Canada that were running at some point in time during 2006 and 2007. This excludes five trials for which the central coordinating site was our home institution.

The median target number of participants to recruit was 226; the median number of sites was 5, and the median percentage of sites that were Canadian was 100%. The number of patients and sites are skewed, with some trials having a much larger recruitment target: the largest trial had 782 sites and a target recruitment of 35,000 participants. There were 498/947 trials (52.6%) funded by academic institutions, government funding agencies, or foundations (henceforth “academic” trials), and the remaining 449/947 trials (47.4%) were funded by industry (henceforth “industry” trials). Therefore, there was a relatively equal split of trials in terms of funding source.

As can be seen in Table 1, industry trials tended to be approximately three times larger in terms of participant recruitment, with substantially more overall sites but proportionally fewer that were Canadian. There were large multicenter academic studies, with the largest academic study having 782 sites of which 14 were in Canada, and the largest industry trial having 757 sites of which 29 were Canadian.

Table 1. Differences between academic and industry trials (two-tailed tests)

	Academic (median)	Industry (median)	*P* value (Mann-Whitney U Test [49])
Number of participants	130	400	< .001
Total sites	1	39	< .001
Canadian sites	100%	11%	< .001

There were 84/947 pediatric-only trials (approximately 9%), and 863/947 adult trials (approximately 91%). In this classification, trials that included adults and youth in their recruitment criteria were classified as adult since they did not focus specifically on a pediatric population. Adult trials were equally likely to be academic as industry (433 vs 430), whereas pediatric trials were much more likely to be academic (chi-square test: $P< .001$).

As can be seen in Table 2, adult trials tended to be almost one and a half times as large as pediatric trials in terms of participant recruitment, with more overall sites but proportionally fewer that were Canadian.

Table 2. Differences between adult and pediatric trials (two-tailed tests)

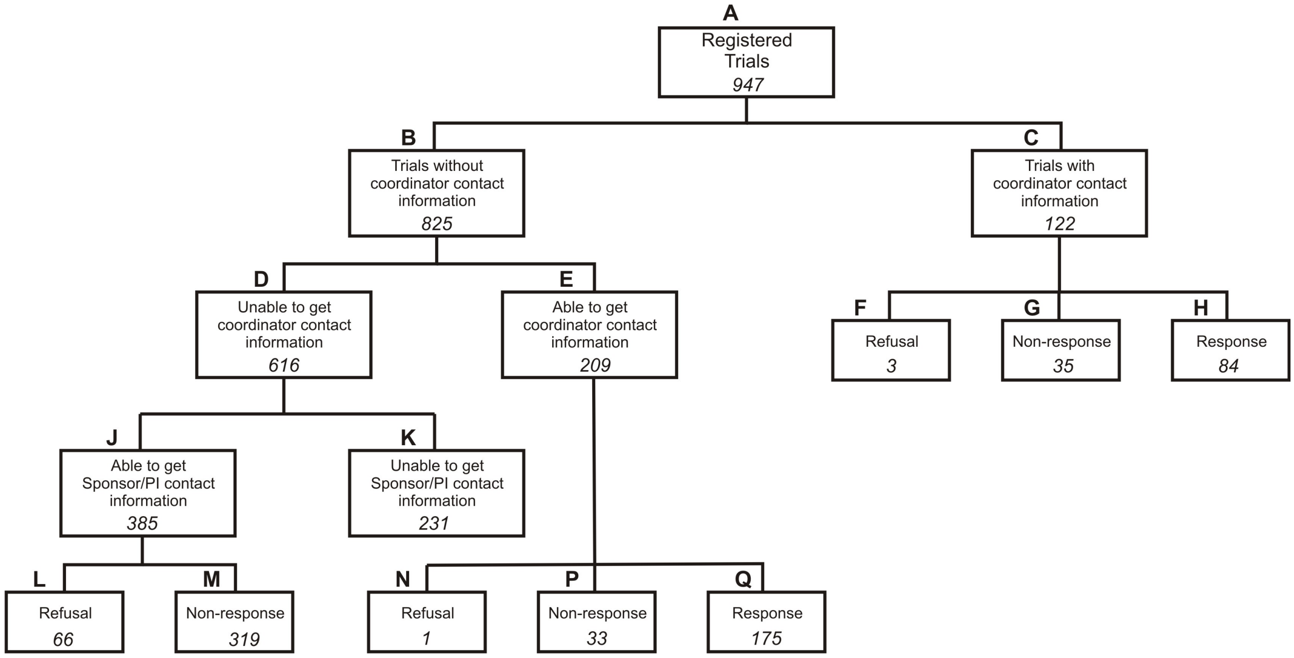
	Adult (median)	Pediatric (median)	*P* value (Mann-Whitney U Test [49])
Number of participants	236	141	< .001
Total sites	6	1	.003
Canadian sites	57%	100%	.001

Response Rate and Nonresponse

As shown in Figure 1, we were able to get study contact information for 716/947 trials (75.6% of the total). These are nodes C, E, and J. C and E represent the 331 trials for which we were able to obtain Canadian site coordinator contact information and that were sent the actual survey. These represent 46.2% of contactable trials (331/716).

Trials for which we did not get contact information tended to be larger industry trials. For some, no contact information was available at all. For others, we had a sponsor or PI contact, whom we followed up with to get Canadian site coordinator contact information. In Figure 1, D represents the trials for which there was insufficient contact information in the registry; for these trials, we tried to get coordinator contact information by contacting the sponsor or PI (J), or it was not possible to get sponsor or PI contact information (K).

Figure 1. Responses to the survey



Reasons given by sponsors or PIs for refusing to provide contact information (node L in Figure 1) included the following: (1) there was a need to get coordinator consent or local site Research Ethics Board approval first before giving us the information because the coordinators would be participating in a research study, (2) the federal privacy legislation (PIPEDA) bars the disclosure of the coordinators' business contact information or that this was confidential (proprietary) information, and (3) the site coordinators do not have time to participate in a survey or the contact does not have time to provide us with the coordinators' contact information.

In all of our subsequent analyses, weights were used to ensure that our responding sample adequately represented the population of Canadian trials [50].

Out of the 331 trials for which we obtained coordinator contacts, 72 did not respond (78% response rate to the survey). We compared those nonrespondents to respondents on the same set of variables. There was no statistically significant difference in the response rates for industry and for academic trials by chi-square criteria. Neither was there a statistically significant difference in response rate for adult trials and for pediatric trials. Furthermore, we did not find any significant differences between survey respondents and nonrespondents on the other three variables (number of patients, number of sites, and proportion of Canadian sites) at a Bonferroni adjusted alpha level of 0.05.

Of the 331 trial coordinators to whom we sent the survey, we wanted to determine if there was a nonresponse bias in terms of their adoption of EDC. A common way to evaluate this is to compare early versus late respondents, where late respondents are a proxy for nonrespondents [51]. We found no significant difference by chi-square criteria.

EDC Adoption Rate

Trials that did not select any of the features were clearly not EDC system users. There was considerable variation in the features of the electronic systems that the remaining trials used. System features can be grouped into six cumulative levels of sophistication (see Table 3): (1) f1, (2) f2 to f4, (3) f5 and f6, (4) f7, (5) f8, and (6) f9. The grouping of features at levels 2 and 3 is done because these features almost always occurred together in EDC systems used by our respondents. We performed a Guttman scaling on the six levels of EDC sophistication. The coefficient of reproducibility for the Guttman scale is 0.901 ($P < .001$), and the coefficient of scalability is 0.79. Such high coefficients provide evidence that the features in EDC systems are cumulative according to our six levels, and therefore the level can be used as a unidimensional score of EDC sophistication.

Based on our definition, systems at a sophistication level of 1 would not be considered an EDC system. For example, if a coordinating center used a password-protected stand-alone database to manually enter paper CRFs that were sent in by courier from other sites, then it would have a system at the first level of sophistication.

Therefore, we only considered systems with a sophistication level of 2 and above as an EDC system. It is estimated that 41% of all trials (95% CI 37.5%-44%) are using an EDC system with a sophistication level of 2 or above.

Table 3. The grouping of features into a six-level cumulative scale of EDC sophistication as determined through a Guttman scalogram analysis: higher levels signify more sophistication

Sophistication Level	Features	
1	f1.	There is a unique account and password for each user to access the online system.
2	f2.	Subject visit data are entered by sites through a Web interface into electronic case report forms (eCRFs).
	f3.	The completion status of each eCRF for each subject can be tracked automatically online; for example, you can see which visits have complete data and which still have incomplete eCRFs for each subject.
	f4.	The system provides an audit trail for all data entry and data modification.
3	f5.	Data validation happens automatically when data are entered into the eCRF (either right away or when the user presses the SUBMIT button), for example, to check for out-of-range values.
	f6.	The system will automatically log the user off after a period of inactivity.
4	f7.	Subjects are randomized automatically, either through an automated telephone response system or through a Web interface.
5	f8.	Subject recruitment can be tracked online for each site; for example, the user can see a graph of recruited and not withdrawn subjects over time.
6	f9.	The system allows tracking of medication inventory at the sites.

The most basic EDC systems in use today have Web-based data entry forms, form completion tracking, and audit trails. Automated randomization is a feature of relatively sophisticated EDC systems. Few trials are able to track subject recruitment over time, and tracking medication inventory is quite uncommon. The median EDC sophistication level was 4 for both academic and industry trials. The median EDC sophistication level for adult trials was 4, and for pediatric trials it was 5. This difference was statistically significant (Mann-Whitney U two-tailed test, $P = .003$).

The logistic regression model to predict EDC adoption had a Nagelkerke R^2 of 0.22. The dummy variable indicating whether the trial was industry or academic was statistically significant (OR = 1.52; one-tailed $P = .002$), and the size variable was also statistically significant (OR = 1.44; one-tailed $P < .001$). Whether a trial had pediatric or adult participants was not significant using a two-tailed test. This suggests that larger trials tended to be more likely to adopt EDC and that industry trials were also more likely to adopt EDC. Whether the trial was adult or pediatric did not make a difference in the adoption of EDC.

Discussion

Summary

The clinical trials landscape in Canada is evenly split between academic and industry trials. However, industry trials tended to be larger with more patients and sites. More than 90% of trials were of adults, and these tended to be larger than pediatric trials. Our results reveal that the 41% adoption rate of EDC systems in Canadian clinical trials is twice the commonly cited value. Larger trials and those sponsored by industry are more likely to use an EDC system. We found that the type of participants did not have an impact on adoption, but this may be because the sample was under-powered to detect this effect given that the distribution of adult/pediatric trials was quite skewed.

While there is no difference in the level of sophistication of EDC systems used between academic and industry trials, pediatric trials tended to have more sophisticated EDC use than those with predominantly adult participants.

It is not surprising that industry-funded trials included in the sample were larger than academic ones. Pharmaceutical companies in Canada invested between $1.1425 billion and $1.67 billion on R&D in 2003 [52,53], of which between $487.5 million and $668 million was on clinical trials [53,54]. These numbers exclude stakeholders such as the biotechnology industry [55] and therefore are expected to be an underestimate. In comparison, the main academic health research funding body in Canada, CIHR, spent only $57 million on clinical trials research during the same period.

To the extent that the need for heavy investments in information technology (IT) can act as a barrier to use, cost would have been a deterrent for academically funded trials to use IT to the same extent as industry trials during the 2006-2007 period that we studied. This concurs with the observation that the median number of sites for academic trials was one; it may be more difficult to justify an investment in EDC for single-site trials. However, recently more EDC systems are adopting the Software as a Service (SaaS) model, where sites access the EDC through their Web browser. Such systems demand less of an IT capacity at each site to get started and do not require a large capital expenditure at the outset of the study to purchase equipment and software licences. Therefore, over time it is plausible that the adoption rate for academic trials will catch up to industry trials.

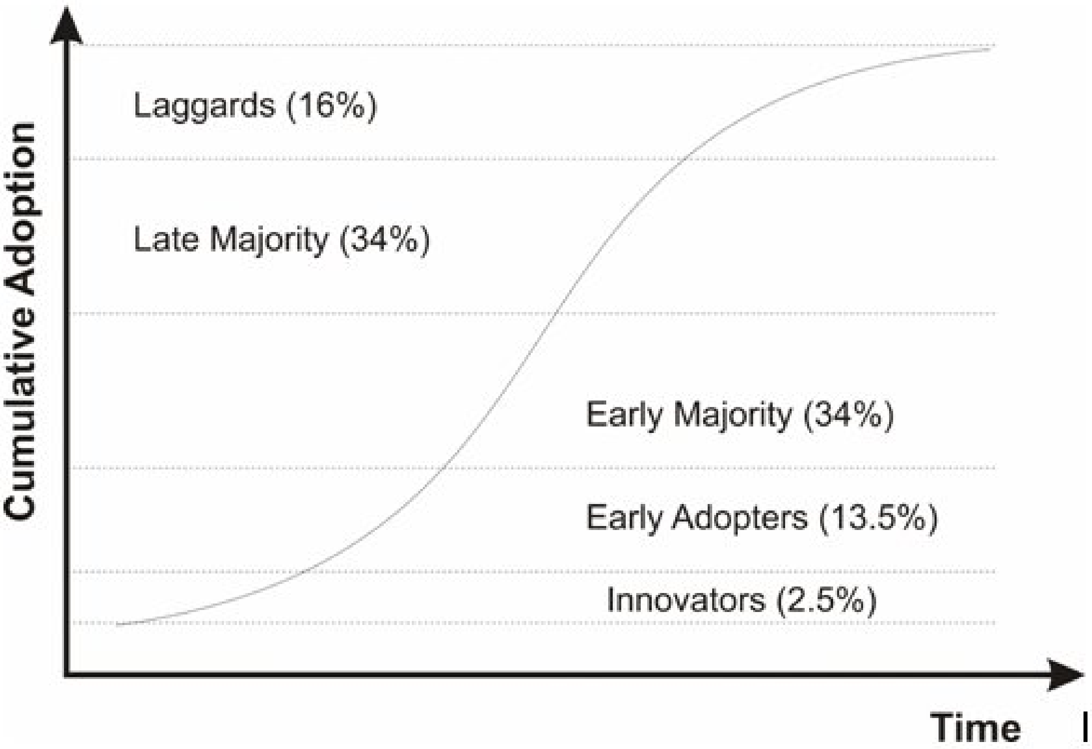
Despite academic trials having a lower adoption rate, there were no differences in terms of the sophistication of the EDC systems that were used by industry-sponsored and academic trials. Therefore, when academic trials do adopt an EDC system, they do not opt for systems with fewer features.

Practical Implications

A commonly accepted descriptive model of the diffusion of innovations is an S-shaped curve, as shown in Figure 2 [56], which characterizes many technological innovations, irrespective of the technology. For example, one study reviewed the adoption patterns of a variety of 20th century consumer products (eg, washing machines, videocassette recorders) and found that they follow the same adoption curve [57], while Teng and Grover developed historical diffusion curves for general information technologies (eg, personal computers, email) [58]. Health care information technologies, including electronic health records, order entry systems, and mobile devices, have also been examined within this diffusion framework [59-63].

To the extent that this model applies to EDC adoption, we are currently in the steepest point of adoption among the early majority of Canadian trials. Consequently, it would be reasonable to expect increased use of EDC systems in trials in the immediate future. This trend is consistent with other evidence showing rising adoption of health IT in general, and specifically, electronic health records [60,64-70], in medical centers and practices.

Figure 2. The S-shaped diffusion of technology curve



High adoption rates of EDC systems have a number of practical and research implications. First, the characteristics of the adopters change over time and so does the nature of suitable evidence to inform their adoption decisions [56]. For example, innovators (the first 2.5% who adopt a new technology) do not need evidence to make an adoption decision. Early adopters (the next 13.5%) are satisfied with case studies and examples of successful adoption and benefits. The early majority require stronger evidence of benefits. There is therefore a strong requirement for more systematic evaluation of EDC systems to quantify the costs and benefits of their use and the contexts in which benefits do or do not materialize in order to address the information needs of the early majority.

Second, EDC systems make it much more practical to make the frequent design changes that are required in adaptive clinical trials [71]. One would therefore expect to see a parallel rise in the use of adaptive trial designs.

Third, for commercial trials, electronic submissions to regulatory authorities would become more practical with the increased use of EDC systems.

Finally, to the extent that EDC improves the data quality and efficiency of trials, higher EDC adoption would be expected to enable such benefits to materialize in the future.

In terms of the EDC systems themselves, the median sophistication level of EDC systems indicates that many trials are not able to track recruitment in real time. This suggests an important feature that EDC developers need to make sure is added to their systems.

Comparison to Previous Work

Our systematic review of the literature (see Multimedia Appendix 1) indicated that only 20% of clinical trials were using an EDC system. It is useful to explore why this number is very different from our results. This large discrepancy can be explained in five possible ways. First, the 20% adoption was true a few years ago and adoption has progressed significantly over the intervening period, reaching the levels we have reported here for 2006-2007. Second, the studies providing the 20% adoption numbers were methodologically weak and therefore this number is unreliable. Third, previous studies used a different unit of analysis—many were reporting on the proportion of pharmaceutical companies and contract research organizations (CROs) that were using EDC rather than the proportion of trials. However, the unit of analysis was often not easily discernable from the published accounts. Fourth, previous studies were not specific to clinical trials in Canada, as opposed to our current results. Finally, previous work did not have a consistent and precise definition of what an EDC system is, and this may have contributed to different surveys not measuring the same thing and classifying systems as EDC differently than us.

It is most likely that reality is a mixture of the above five reasons.

Future Work

It would be of value to track the adoption of EDC over time using regular surveys similar to the current one. This will provide evidence as to whether the adoption is actually following the S-shaped adoption curve in Figure 2 as we have postulated.

Additional comparisons with the United States and Europe would be informative. If there are significant regional differences in adoption rates, then there may be policy or structural choices that explain the differential. For example, if one region has adopted a certain set of policies or incentives, or has an existing health informatics infrastructure that supports the use of EDC, then other regions may consider duplicating those drivers to accelerate their EDC adoption rates.

There are other factors that could have an impact on the adoption of EDC that would be useful to investigate in future research. For example, for academically funded trials, one would consider the age of the PI, his or her technical skill/knowledge, the existence of a senior informatics person to provide support, whether there is an existing research systems infrastructure in place with programming or database resources available for investigators to use, and whether or not the academic institution already has a sophisticated EDC system available for use by any investigators. For industry-funded trials, one could consider the size of the organization running the trial (whether it is the industry sponsor or a CRO), the size of trials usually conducted, and the number of trials conducted per year in the geographical region of study (say, Canada or the United States).

Since we have developed an EDC sophistication measure, it would now be easier to evaluate the relationship between EDC sophistication and the benefits of EDC. One can hypothesize that more sophisticated EDC use will be associated with greater benefits, such as faster trial completion and fewer data errors.

Limitations

One limitation of our results is that individuals conducting clinical trials may not have registered their trials [40], suggesting that some investigator-initiated trials may not be in the registries. If that is indeed the case for trials with sites in Canada, then unregistered trials may introduce a bias if they differ systematically in terms of their adoption of EDC technology and/or size.

Our results are limited to Canada, and the adoption rates may be different in other jurisdictions.

Acknowledgments

We wish to thank the reviewers for their valuable feedback on an earlier version of this paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Systematic Review of EDC Adoption Surveys

[PDF file(Adobe PDF), 201KB - jmir_v11i1e8_app1.pdf]

Multimedia Appendix 2

Questionnaire Development and Validation

[PDF file(Adobe PDF), 131KB - jmir_v11i1e8_app2.pdf]

Multimedia Appendix 3

CHERRIES Summary

[PDF file(Adobe PDF), 96KB - jmir_v11i1e8_app3.pdf]

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Abbreviations

CIHR: Canadian Institutes of Health Research
CRF: case report form
CRO: contract research organization
eCRF: electronic case report form
EDC: electronic data capture
FDA: Food and Drug Administration
ISRCTN: International Standard Randomised Controlled Trial Number
IT: information technology
PI: principal investigator

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Original Paper

Using the Internet for Health-Related Activities: Findings From a National Probability Sample

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Abstract

Background: eHealth tools on the Internet have the potential to help people manage their health and health care. However, little is known about the distribution and use of different kinds of eHealth tools across the population or within population subgroups.

Objective: The purpose of this study was to examine the prevalence and predictors of participation in specific online health-related activities.

Methods: A secondary data analysis of the National Cancer Institute’s Health Information National Trends Survey (HINTS) 2005 was conducted to study three online behaviors among Internet users (n = 3244): searching for health information for oneself, participating in a support group for those with similar health or medical conditions, and purchasing medicine or vitamins.

Results: A total of 58% of Internet users reported searching for health information for themselves, 3.8% used online support groups, and 12.8% bought medicine or vitamins online in the past year. Multivariate analysis found that those seeking health information were more likely to be women (OR = 2.23, 95% CI = 1.60, 3.09), have cable or satellite Internet connections (OR = 1.73, 95% CI = 1.22, 2.45) or DSL connections (OR = 1.94, 95% CI = 1.36, 2.76), have Internet access from work (OR = 2.43, 95% CI = 1.27, 4.67) or from home and work (OR = 1.73, 95% CI = 1.31, 2.30), and report more hours of weekday Internet use (OR = 4.12, 95% CI = 2.41, 7.07). Those with a high school education or less (OR = 0.44, 95% CI = 0.31, 0.63) and those with some college (OR = 0.66, 95% CI = 0.49, 0.89) were less likely to search for health information. Online support groups were more likely to be used by those with “fair” health (OR = 3.28, 95% CI = 1.21, 8.92) and “poor” health (OR = 5.98, 95% CI = 1.49, 24.07) and those with lower incomes (OR = 2.64, 95% CI = 1.09, 6.41) and less likely to be used by those with Internet access both at home and work (OR = 0.56, 95% CI = 0.35, 0.90). Those who were age 35-49 (OR = 2.16, 95% CI = 1.43, 3.26), age 50-64 (OR = 2.44, 95% CI = 1.53, 3.89), and age 65-74 (OR = 2.18, 95% CI = 1.30, 3.67) and those who were married (OR = 1.93, 95% CI = 1.13, 3.30) were more likely to purchase medicine or vitamins online.

Conclusions: The Internet was most widely used as a health information resource, with less participation in the purchase of medicine and vitamins and in online support groups. Results suggest that modifying survey questions to better capture forms of online support and medications purchased could provide greater understanding of the nature of participation in these activities.

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KEYWORDS

Internet; Web; health behavior; consumer

Introduction

The purpose of this study was to examine the prevalence and predictors of participation in online health-related behaviors. Millions of people are now using the Internet on a regular basis, and much of this activity has been focused on health. Online eHealth tools have the potential to help people manage their health and health care, but little is known about the use of different kinds of eHealth tools across the population [1,2]. In 2003, an estimated 12.5 million online health-related searches were conducted globally each day [3]. However, aggregate figures like this do not tell us about what people are actually doing when they interact with online health-related content and tools. This study examined participation in three different online activities—health or medical information-seeking for oneself, use of online support groups for people with similar health and medical issues, and online purchase of medicine and vitamins—in order to better understand the potential of different health-related activities to influence people's lives.

Understanding how people use the Internet for health-related activities can be critical to the design of relevant sites in order to attract and retain users [4]. One of the first steps in developing both traditional and computer-based health communication is an analysis of the target audience [5,6] to identify the audience's preferences and needs and influence product acceptance and utilization [6]. Further, analysis of differential use of Internet applications by subpopulations can serve to identify potentially underserved groups and allow for the development of strategies to meet their needs [2].

Eysenbach [3] identified four broad applications of the Internet: (1) content (eg, information seeking), (2) community (eg, bulletin boards, chat rooms), (3) communication (eg, email), and (4) e-commerce (eg, buying or selling products and services on the Internet). The most commonly reported function for health has been content, or searching for health and medical information on the Internet [7]. Fewer Internet users have reported engaging in the other three functions for health-related purposes [7]. A recent study examined one health-related communication application—emailing a health care provider—and found a slow, but significant, increase in the prevalence of this activity from 2003 to 2005 (7% to 10% of Internet-using adults emailing a health care provider in the past year) [8]. The present study focused on health-related activities related to the other application areas of content, community, and e-commerce.

Content

In 2000, 47% of Internet users reported that they looked for health information for themselves during their last online search [7]. Certain groups are more likely to search for health information: women [9,10] and those with higher education [9,10], a chronic health condition [10], more years of Internet experience [9], and broadband access [9]. The effect of income and age on online health information seeking has been inconsistent across studies [2,7,9,10]. No studies examining general Internet use have demonstrated racial/ethnic differences among those who seek health information online, but racial/ethnic differences have been found in the preferences and usage of content and community functions within specific online intervention and support programs [11-14]. For example, research examining the impact of a computer-based support system, the Comprehensive Health Enhancement Support System (CHESS), found that minority women with breast cancer spent more time using informational and decision-support features and were less likely to use the discussion groups than white women [11-13].

Community

Few Internet users have reported contacting an online support group for a medical condition or personal problem—only 28% in 2001 [15]. At that time, women between the ages of 35 and 44 were more likely to participate in Internet groups to help manage daily responsibilities, including medical conditions. In 2005, participation in online chat rooms in general dropped to as low as 17% [16], which was attributed to a drop-off in women's participation because of an increased concern about "worrisome" behavior in chat rooms.

Commerce

Purchasing medications and vitamins online can be convenient and cost-effective [17], but this activity has occurred with low frequency thus far. In 2001, only about 5% of respondents had ever purchased prescription drugs online [18,19]. Three years later, only 4% of American adults reported ever purchasing drugs online [19]. However, one fourth (26%) of American adults reported looking on the Internet for information about prescription drugs in the same time period. Those with higher incomes and more years of Internet experience were more likely to purchase drugs online [19]. Most were satisfied with their purchase and reported that they would purchase drugs online again in the future, suggesting that the prevalence of this activity may increase.

These studies indicate that the use of the Internet for health reasons varies across population subgroups by the types of tools and services used and the frequency with which they are used. Ongoing research is needed to increase understanding about people's preferences when using the Internet as a whole and to see how their use of these features changes over time. Further research is also needed to monitor activities, such as online purchase of medications [19]. Although few people are currently reporting participation in these activities, they have the potential to impact how people manage their health. Continued research can provide additional evidence about the nature of these online behaviors and determine whether their use will diffuse to a more general Internet-using population.

The present study was a secondary data analysis that examined the prevalence of specific health-related online activities and whether sociodemographic, health status, and Internet use factors were related to participation in these activities. The health-related Internet activities used in this study corresponded to Eysenbach's application areas of content, community, and commerce [3]. Specifically, the research questions were (1) What is the prevalence of health or medical information seeking for oneself, use of online support groups for people with similar health and medical issues, and online purchase of medicine and vitamins? and (2) Are sociodemographic, health status, and

Internet use differences related to participation in each of the three activities?

Methods

This study analyzed data from the National Cancer Institute's Health Information National Trends Survey (HINTS) 2005 to answer the research questions. The HINTS survey collects nationally representative data about the US public's cancer communication practices, information preferences, risk behaviors, attitudes, and cancer knowledge [20]. The HINTS survey has been administered twice, first in 2003 and then again in 2005.

Participants in the 2005 survey (n = 5586) were recruited via random digit dialing of all telephone exchanges throughout the United States and then randomly selected from among the adults in the household. Survey administration averaged 30 minutes per participant. Response rates were 34% at the household screening level and 61% at the sampled person interview level [21].

All analyses were conducted using STATA Version 9 [22] to properly calculate standard errors for the multistage sampling design. The present analyses were conducted on the subset of the sample who reported going online, based on their response to the item "Do you ever go online to access the Internet or World Wide Web, or to send and receive e-mail?" All results were weighted to be representative of the United States adult population. To correctly calculate standard errors for the subset of adult Internet users residing in the United States, the SUBPOP statement in STATA Version 9 was used.

Descriptive statistics were calculated for all variables. Logistic regression analyses were conducted to answer the research question of whether selected sociodemographic, health status, and Internet use variables predict the Internet behaviors of looking for health information, participating in an online support group, or purchasing medicines or vitamins online.

HINTS questionnaire items were used to measure the following demographic variables: age, gender, ethnicity and race, education, income, marital status, number of children under 18 years in the home, general health status, and cancer history. Data for each variable were grouped into categories consistent with other research using HINTS data [23-25]. Additional items were selected in order to measure factors related to Internet use: location of access, type of connection, and frequency of use. Outcome variables measured use of the Internet for personal health information, use of online communities, and the purchase of medications or vitamins.

The unknown rates, which included missing, don't know, or refused responses, were less than 4% for all variables except income. For all variables except income, unknowns were removed from the denominators when calculating percents. In the regression analyses, all unknowns, except those for income, were excluded from all of the models run and the subsequent results that are presented. Because of the relatively large number of respondents with unknown income, "unknown" was included in the regression analysis as a separate category. The HINTS questionnaire can be viewed at the National Cancer Institute's website [26].

Results

Characteristics of the Sample Population

Over half (58%) of the sample, or 3244 respondents, reported that they used the Internet. The findings indicated that respondents were largely under age 50, non-Hispanic white, married, with some college education and annual incomes over US$50,000. The sociodemographic, health, and Internet use characteristics are summarized in Table 1.

Almost 90% of these Internet users reported Internet access at home, with 41% using a dial-up connection and almost 50% reporting high-speed connections. Over 60% of Internet users reported that they typically use the Internet for an hour on weekdays. These results suggest that using the Internet has become a ubiquitous part of daily life for many Americans. See Table 1 for a summary of Internet use characteristics.

Table 1. Sociodemographic, health, and Internet use characteristics of Internet users (n = 3244)

Characteristic	No.	Weighted Percent[a,b]
Age		
18-34	785	37.7
35-49	1076	33.3
50-64	958	22.1
65-74	301	5.0
75 and older	119	2.0
Gender		
Male	1169	48.2
Female	2075	51.8
Race/ethnicity		
Non-Hispanic white	2592	76.6
Non-Hispanic black	209	8.9
Hispanic	176	7.6
Non-Hispanic other	122	4.6
Multiple races	54	2.4
Education		
Less than high school	113	5.3
High school graduate	594	23.6
Some college	1029	38.3
Bachelor’s degree or higher	1430	32.8
Household income		
< $25,000	364	11.8
$25,000-$50,000	665	18.3
> $50,000	1770	55.7
Unknown	445	14.2
Marital status		
Married or living with a partner	2055	66.0
Divorced, widowed, or separated	584	9.7
Never married	521	24.3
Household members under 18 years		
None	1997	55.0
1 child	503	18.7
2 children	501	17.4
3 or more children	243	8.9
General health status		
Excellent	460	13.4
Very good	1157	33.3
Good	1070	37.0
Fair	405	13.8
Poor	85	2.6
Cancer history: self		
Yes	429	9.8

Characteristic	No.	Weighted Percent[a,b]
No	2812	90.2
Location of access		
Home only	1743	51.3
Home and other	179	9.1
Work only	195	4.9
Work and other	30	1.2
Home and work	856	24.4
Home, work, and other	76	2.9
Other location, not including home or work	161	6.0
Type of Internet connection		
Dial-up	1369	41.0
Cable or satellite	791	25.7
DSL	707	22.8
Other	254	7.1
Weekday hours online		
None	117	3.7
1 hour	2069	62.4
2 hour	527	17.4
3 hours	174	6.7
4 or more hours	245	9.9
Weekend hours online		
None	436	12.9
1 hour	1204	37.2
2 hour	666	20.2
3 hours	253	8.7
4 or more hours	576	20.9

[a] Results are weighted to be representative of the adult population of Internet users residing in the United States.

[b] Except for household income, unknown responses (“refused, “don’t know”) were excluded from the calculation of the percents shown in this table. The unknown rates for all characteristics besides household income were less than 4%.

Prevalence of Health-Related Internet Activities

The most prevalent of the three studied activities was looking for health information for oneself, with 58.5% of respondents reporting that they had done so in the past 12 months. The other online activities occurred with lower frequency: 3.8% reported using an online support group for people with a similar health or medical issue, and 12.8% reported buying medicine or vitamins online.

Determinants of Health-Related Internet Activities

Generally, each activity was predicted by a unique set of variables. Table 2 shows the results of the multivariate logistic regression analyses for each of the three online health activities.

Table 2. Multivariate logistic regression of predictors of participation in online health-related activities in the past 12 months (n = 3244)[a]

	Search for Health Information		Use Support Group		Buy Medicines or Vitamins	
	OR (95% CI)	*P*[b]	OR (95% CI)	*P*[b]	OR (95% CI)	*P*[b]
Age		.73		.28		.001
18-34	1.00		1.00		1.00	
35-49	1.13 (0.83, 1.54)		1.84 (0.82, 4.13)		2.16 (1.43, 3.26)[e]	
50-64	1.01 (0.73, 1.40)		1.64 (0.76, 3.52)		2.44 (1.53, 3.89)[e]	
65-74	0.92 (0.55, 1.53)		0.70 (0.13, 3.71)		2.18 (1.30, 3.67)[e]	
75 and older	0.75 (0.41, 1.38)		0.81 (0.19, 3.45)		1.65 (0.72, 3.81)	
Gender		< .001		.07		.23
Male	1.00		1.00		1.00	
Female	2.23 (1.60, 3.09)[e]		1.67 (0.96, 2.92)		1.21 (0.89, 1.64)[e]	
Race/ethnicity		.33		.98		.72
Non-Hispanic white	1.00		1.00		1.00	
Non-Hispanic black	0.72 (0.50, 1.04)		1.29 (0.34, 4.90)		1.25 (0.71, 2.20)	
Hispanic	1.02 (0.65, 1.61)		0.84 (0.19, 3.65)		0.92 (0.44, 1.94)	
Non-Hispanic other	0.83 (0.40, 1.70)		0.99 (0.34, 2.85)		0.82 (0.36, 1.87)	
Multiracial	1.58 (0.54, 4.64)		0.63 (0.06, 6.92)		1.84 (0.67, 5.01)	
Education		< .001		.06		.91
Bachelor’s degree and higher	1.00		1.00		1.00	
Some college	0.66 (0.49, 0.89)[e]		0.71 (0.40, 1.25)		0.98 (0.69, 1.38)	
High school or below	0.44 (0.31, 0.63)[e]		0.42 (0.20, 0.88)		0.91 (0.61, 1.37)	
Household income[c]		.15		.04		.39
$50,000 and higher	1.00		1.00		1.00	
$25,000-49,999	0.90 (0.64, 1.27)		1.32 (0.68. 2.58)		1.16 (0.73, 1.84)	
Less than $25,000	1.42 (0.96, 2.09)		2.64 (1.09, 6.41)[d]		1.11 (0.66, 1.86)	
Marital status		.77		.52		.03
Never married	1.00		1.00		1.00	
Married/living with partner	1.16 (0.76, 1.77)		1.66 (0.68, 4.05)		1.93 (1.13, 3.30)[d]	
Divorced/widowed/separated	1.12 (0.68, 1.84)		1.81 (0.57, 5.69)		1.47 (0.80, 2.74)	
Household members < 18 years		.01		.35		.14
None	1.00		1.00		1.00	
1 child	0.94 (0.68, 1.28)		0.60 (0.30, 1.20)		0.90 (0.61, 1.33)	
2 children	0.82 (0.53, 1.28)		0.78 (0.40, 1.51)		0.63 (0.40, 0.98)	
3 or more children	0.54 (0.38, 0.77)[e]		1.31 (0.59, 2.92)		0.57 (0.28, 1.16)	
General health status		.06		.01		.19
Excellent	1.00		1.00		1.00	
Very good	1.07 (0.74, 1.55)		1.27 (0.56, 2.89)		1.28 (0.84, 1.95)	
Good	1.39 (0.99, 1.94)		1.18 (0.49, 2.88)		1.03 (0.64, 1.66)	

	Search for Health Information		Use Support Group		Buy Medicines or Vitamins	
	OR (95% CI)	P [b]	OR (95% CI)	P [b]	OR (95% CI)	P [b]
Fair	1.42 (0.86, 2.33)		3.28 (1.21, 8.92)[e]		0.68 (0.38, 1.20)	
Poor	2.21 (0.61, 8.04)		5.98 (1.49, 24.07)[e]		1.27 (0.52, 3.07)	
Cancer history: self		.09		.34		.47
No	1.00		1.00		1.00	
Yes	1.39 (0.95, 2.03)		0.75 (0.42, 1.36)		0.86 (0.57, 1.30)[d]	
Location of access		.002		.05		.36
Home[f]	1.00		1.00		1.00	
Work[g]	2.43 (1.27, 4.67)[e]		2.28 (0.56, 9.19)		0.60 (0.25, 1.47)	
Home and work[h]	1.73 (1.31, 2.30)[e]		0.56 (0.35, 0.90)[d]		0.97 (0.72, 1.30)	
Other[i]	1.24 (0.57, 2.71)		1.38 (0.18, 10.45)		0.71 (0.19, 2.65)	
Internet connection [c]		.003		.68		.36
Dial-up	1.00		1.00		1.00	
Cable or satellite	1.73 (1.22, 2.45)[e]		0.98 (0.45, 2.12)		1.48 (0.95, 2.30)	
DSL	1.94 (1.36, 2.76)[e]		1.41 (0.74, 2.67)		1.46 (0.98, 2.19)	
Other	1.17 (0.66, 2.07)		0.49 (0.12, 2.05)		1.54 (0.70, 3.39)	
Weekday hours online		< .001		.08		.42
None	1.00		1.00		1.00	
1 hour	4.12 (2.41, 7.07)[e]		2.85 (0.25, 32.91)		1.78 (0.75, 4.23)	
2 hours	6.05 (3.18, 11.49)[e]		7.33 (0.56, 96.35)		2.15 (0.84, 5.52)	
3 hours	6.42 (2.53, 16.32)[e]		3.51 (0.24, 50.73)		2.75 (0.84, 8.98)	
4 or more hours	4.46 (1.56, 12.71)[e]		3.46 (0.22, 54.67)		1.79 (0.65, 4.96)	
Weekend hours online		.39		.42		.63
None	1.00		1.00		1.00	
1 hour	1.08 (0.69, 1.71)		2.03 (0.49, 8.44)		0.91 (0.56, 1.48)	
2 hours	1.25 (0.74, 2.10)		2.33 (0.48, 11.31)		0.93 (0.52, 1.66)	
3 hours	1.29 (0.64, 2.59)		1.05 (0.17, 6.44)		1.12 (0.58, 2.16)	
4 or more hours	1.79 (0.91, 3.55)		2.22 (0.35, 14.08)		1.28 (0.74, 2.21)	

[a] Results are weighted to be representative of the adult population of Internet users residing in the United States.

[b] *P* values associated with Wald statistic.

[c] Analyses included unknown (“refused,” “don’t know”) responses that are not shown in the table.

[d] *P* value is significant to the .05 level (*P* < .05).

[e] *P* value is significant to the .01 level (*P* < .01).

[f] Includes “home only” and “home and other” responses.

[g] Includes “work only” and “work and other” responses.

[h] Includes “home and work only” and “home, work, and other” responses.

[i] Includes locations other than home or work.

Searching for Health Information for Oneself

Logistic regression analysis showed that gender, education, having children under age 18, location of Internet access, type of Internet connection, and hours of weekday Internet use predicted who was likely to search for health information. Women were more likely than men (OR [odds ratio] = 2.23, 95% CI [confidence interval] =1.60, 3.09) to search for health information. Those with a high school education or less (OR = 0.44, 95% CI = 0.31, 0.63) and those with some college education (OR = 0.66, 95% CI = 0.49, 0.89) were less likely to search for health information than those with a bachelor’s degree or higher. Those with three or more children under the age of 18 were less likely to look for health information for themselves than those with no children in the home (OR = 0.54, 95% CI = 0.38, 0.77).

Respondents with access from work (OR = 2.43, 95% CI = 1.27, 4.67) and access from home and work (OR = 1.73, 95% CI = 1.31, 2.30) were more likely to search for personal health information than those with primarily home access. Those with cable or satellite Internet connections (OR = 1.73, 95% CI = 1.22, 2.45) or DSL connections (OR = 1.94, 95% CI = 1.36, 2.76) were also more likely to search for personal health information than those with dial-up connections. Those who used the Internet for 1 hour or more on weekdays were more than four times as likely to search for health information as those who did not report daily Internet use.

Use of an Online Support Group

Health status, location of access, and income significantly predicted the use of online support groups for people with similar health or medical issues. Those who reported their health to be "fair" were 3.28 times as likely (95% CI = 1.21, 8.92) to use online support groups than those reporting their health to be "excellent." Similarly, those with "poor" health were 5.98 times as likely (95% CI = 1.49, 24.07) to use online support than those in "excellent" health. Respondents with access from both home and work were about half as likely to use online support groups as those with access primarily from home (OR = 0.56, CI = 0.35, 0.90). Those with incomes lower than US$25,000 were more than twice as likely as those with incomes greater than US$50,000 to use online support groups (OR = 2.64, 95% CI = 1.09, 6.41).

Buying Medicines or Vitamins Online

Only two variables predicted the online purchase of medicines or vitamins: age and marital status. Adult Internet users ages 35-49, 50-64, and 65-74 were about twice as likely as users ages 18-34 to make these online purchases. Respondents who were married or living with a partner were almost twice as likely (OR = 1.93, 95% CI = 1.13, 3.30) as those who were never married to purchase medicines or vitamins online.

Discussion

This study examined the prevalence of participation in online health activities and whether participation in these activities is predicted by sociodemographic, health status, and Internet use factors. We found that participation in these activities varied and that different sets of variables predicted who was likely to engage in these different activities.

Almost 60% of the Internet users surveyed reported searching for health information for themselves in the previous year. Fox and Rainie [7] identified the search for health information as the most common online health-related activity, and the present study found it to be the most prevalent of the three studied behaviors. This finding has several critical implications for both information providers and seekers. First, health agencies can use findings such as these to justify making health information available online because many people are using this channel, often before talking to their clinicians. Although people may prefer to go to their clinicians first, they have reported that they actually go online first for health information [27].

However, just making information available is not sufficient. Health agencies need to take responsibility for understanding how best to meet the needs of online information seekers. The rate of Internet use and broadband adoption has continued to increase among those with less than a high school education [28], suggesting that the number of users with lower literacy levels will grow [29]. Although this study found that respondents with higher education were more likely to search for health information, people with low literacy have identified health information as one of the primary types of information for which they would search [30]. Given that much of the health information on the Internet has been written at too high a level for many population segments [1], the development of materials that can be used and understood by audiences with lower literacy levels will be critical.

Another implication of online health information seeking relates to whether consumers can assess the quality of online health information. Despite the existence of reputable health portals, most users begin their search from a search engine [7] and rarely go beyond the first page of returned results [31]. Consumers must possess the skills to sort through and critically evaluate online information if the Internet is to realize its full potential in helping people meet their information needs.

Health status has been associated with health-related Internet use in previous studies [3,10], but these studies have reported conflicting evidence on whether having a chronic condition predicted health information seeking on the Internet. This study found that neither health status nor having been diagnosed with cancer were associated with greater Internet use for health information seeking. However, on the HINTS survey, respondents who indicated that they had been diagnosed with cancer could currently be in remission and not actively coping with a current cancer diagnosis. Thus, the use of this variable as a proxy measure of health status may not truly distinguish healthier versus less healthy individuals.

Health information seeking was also predicted by Internet use variables. Although almost all (90%) users had Internet access from home, this study found that those with access primarily from work or from both home and work were more likely to search for health information for themselves. People were more likely to use the Internet to search for health information if they used the Internet for an hour or more on typical weekdays and, as in previous research [9], had faster connections.

Having Internet access in the home has been considered an important indicator of equitable access among population groups [32], but the current results suggest that work access may be a critical factor in using the Internet for health information seeking. Frequency of use on weekdays and not weekends was related to searching for health information, again suggesting use on typical workdays. Accessing the Internet from work may offer some users faster connections. Given that most contact with medical professionals occurs during traditional work hours, receiving a phone call at work with a new diagnosis or lab results may provide a cue to action for an Internet search for those with the means to immediately begin searching. Those with access from both home and work may simply have more opportunities to search for health information.

The use of online support groups for people with a similar health or medical condition occurred with the lowest prevalence, with only 3.8% of participants reporting participation in such a group. Online support group use appears to be an infrequent activity, and the low rate of participation in health-related support groups may coincide with the general decline in online chat room participation reported by Fallows [16]. However, this finding may also result from the survey methodology. The HINTS survey question asked only about participation in online support groups; however, people may use Internet forums, bulletin boards, online communities, mailing lists, chat rooms, wikis, and blogs as means of providing or receiving online support or to share information. Users may not identify experiences with these different varieties of online communication as "participation in an online support group," so this study may be underestimating the prevalence of Internet use for social support. Future surveys should first ask generally about use of the Internet for health-related social support and follow up with questions asking about specific mechanisms (eg, message boards, blogs) for getting support.

The present study found that those reporting "fair" or "poor" health were more likely to use online support groups than those with "excellent" health. This suggests that those with greater health needs appear to be taking greater advantage of the Internet to help them cope with their conditions, even though online support groups usage was limited overall.

Those with lower incomes were also more likely to use online support groups, although previous studies found that those with higher incomes were more likely to search for health information [10] or purchase medications online [19]. Possibly, those with higher incomes have other means of support, while those with lower incomes are turning to the Internet for assistance. An implication of this finding may be that people with limited incomes are replacing medical care with online support groups, which may put them at risk if they do not get needed assessments and treatment. However, this finding could also be the result of statistical error based on the low rate of participation in this activity overall as well as the high number who did not report their income.

Respondents with Internet access only from their home were more likely to use online support groups than those with access at both home and work, suggesting that those who were "less connected" may have greater need for online support. Continued research on the impact of location of Internet access and use of online social support tools is needed to understand and validate this relationship.

Almost 13% of respondents reported purchasing medications or vitamins online, which is much higher than the 4% and 5% reported in previous studies [18,19] and the 9% in the 2003 HINTS survey [33]. Given the potential for negative outcomes if poor oversight and regulation of this activity occur, research on the impact of the online purchase of medications and vitamins could be expanded so that we better understand the nature of this behavior. In contrast to Fox's [19] finding that income and years of Internet experience predicted online medication purchase, this study found only age and marital status to be significant predictors. This activity may have increased recently because of national discussions about prescription drugs and increased interest in complementary and alternative medicine. It may also reflect the increase in use of the Internet for e-commerce in general [34].

Across online health-related activities, this study examined the relative importance of specific sociodemographic variables. One of the variables most connected with these activities was gender. The current research found that women were more likely than men to engage in a search for health information for themselves. They were equally as likely as men to participate in online support groups and to purchase medications and vitamins. However, married participants were more likely to purchase medications and vitamins online, indicating that women may have additional influence on this behavior.

Traditionally, men have been less likely than women to engage in health information seeking and preventive health behaviors. Since men do use the Internet for so many other activities, perhaps the Internet provides an opportunity to provide non-traditional health education opportunities directed toward men. A comparative content analysis of existing websites for men's and women's health is needed to determine gaps in such resources. Continued formative research could also help determine the types of health-related sites or online formats that would better appeal to male audiences.

Despite implications from other Internet intervention studies [11-14], racial and ethnic minorities appeared to engage in health-related activities at rates similar as white users. These results may suggest that use of the World Wide Web is different than use of Internet-based systems on which these studies have been conducted. Even though African American and Hispanic populations have long shown lower rates of Internet adoption as compared to white users [32,35,36], the current research suggests that once online, they are as likely as white users to engage in health-related activities. Ongoing research is needed to understand the patterns of use by different subpopulations.

Limitations

This study was limited by its examination of only three select online activities. People may be engaging in many other online activities, such as searching for health information for others, using online behavior change or disease management programs, locating a health care provider, or researching health insurance plans. The Internet also offers several new ways to interact with other people via social media not captured by the current HINTS survey. Further examination of these additional activities would provide a larger window into the use of the Internet for health purposes. A second limitation of this study was that it only included data from those who were online. Comparing those who are online to those who are offline could further identify subgroup differences and differential information needs.

This study was also limited by nature of the HINTS data. The response rate, which has declined from the 2003 HINTS survey, may mean that systematic differences exist between those who responded and those who did not. In addition, the data are based on self-report, which can be biased by social desirability.

Conclusion

In conclusion, this study found that, in the context of health, the Internet is still most widely used as an information resource, with much less use for the purchase of medications and vitamins and participation in online support groups. As the types of tools and activities available to Internet users expand, the tools to monitor their use must also expand. Modifying and adding survey items would enable better measurement of Internet participation, especially in online support and social media mechanisms that could not be determined in the current research. Added items would also reveal the types of medications and vitamins people obtained online and show whether additional consumer safety and patient education information needs exist.

This study found that having access to the Internet from both home and work increased the likelihood of searching for personal health information and decreased the likelihood of participating in online support groups, indicating the need to understand more about the impact of work access. Future studies using HINTS data could determine the importance of other predictive variables. For example, these data could be used to examine whether people who use online support groups are less likely to be employed or if people who are employed are less likely to use support groups overall. This kind of research has the potential to distinguish the role of employment status from having access to the Internet at work.

Women continue to be the most likely audience for health-related online activities, while racial and ethnic minorities had rates higher than expected. Further research should be conducted into strategies to reach other audiences or to determine which channels may better serve those who do not use the Internet for health. Now that HINTS has been administered in 2003 and 2005 and another administration is being completed, future research will be possible to identify trends in participation in these and new online health behaviors.

Conflicts of Interest

None declared.

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Abbreviations

HINTS: Health Information National Trends Survey

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Original Paper

Assessment of Pictographs Developed Through a Participatory Design Process Using an Online Survey Tool

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Abstract

Background: Inpatient discharge instructions are a mandatory requirement of the Centers for Medicare and Medicaid Services and Joint Commission on Accreditation of Healthcare Organizations. The instructions include all the information relevant to post-discharge patient care. Prior studies show that patients often cannot fully understand or remember all the instructions. To address this issue, we have previously conducted a pilot study in which pictographs were created through a participatory design process to facilitate the comprehension and recall of discharge instructions.

Objective: The main objective of this study was to verify the individual effectiveness of pictographs created through a participatory design process.

Methods: In this study, we included 20 pictographs developed by our group and 20 pictographs developed by the Robert Wood Johnson Foundation as a reference baseline for pictographic recognition. To assess whether the participants could recognize the meaning of the pictographs, we designed an asymmetrical pictograph–text label-linking test. Data collection lasted for 7 days after the email invitation. A total of 44 people accessed the survey site. We excluded 7 participants who completed less than 50% of the survey. A total of 719 answers from 37 participants were analyzed.

Results: The analysis showed that the participants recognized the pictographs developed in-house significantly better than those included in the study as a baseline ($P < .001$). This trend was true regardless of the participant's gender, age, and education level. The results also revealed that there is a large variance in the quality of the pictographs developed using the same design process—the recognition rate ranged from below 50% to above 90%.

Conclusions: This study confirmed that the majority of the pictographs developed in a participatory design process involving a small number of nurses and consumers were recognizable by a larger number of consumers. The variance in recognition rates suggests that pictographs should be assessed individually before being evaluated within the context of an application.

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KEYWORDS

Discharge instructions; patient communication; pictograph; readability; health literacy

Introduction

Centers for Medicare and Medicaid Services (CMS) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) require that, upon discharge, all inpatients receive detailed instructions for self-care management [1,2]. The delivery of discharge instructions to a patient is the culmination of a complex process. The planning and assessment of discharge instructions begin with the patient’s first visit and continue until the patient leaves the hospital. Typically, patients receive the instructions both orally and in writing. Upon discharge, a nurse reads and explains the written instructions to make sure the patient understands them. The patient keeps a copy of the written instructions for later consultation. The instructions include all the information relevant to post-discharge patient care.

Despite this duplication of information, some studies show that patients often cannot fully understand or remember all the instructions [3-5]. Research also shows that this lack of comprehension affects patient satisfaction and compliance [6-8]. Comprehension of medical instructions can be especially challenging for people with lower reading skills. The average reading skill level of the adult population in the United States is estimated to be between the 8th and 9th grade level [9]. However, recent studies show that more than half of medical instructions are written at levels higher than the 10th grade [10-12]. A study on Medicare enrollees reported that about 23% of English-speaking enrollees could not adequately understand medical instructions written in English [13].

In addition to the complexity of the instructions, factors such as physical and emotional distress, lack of motivation, and environmental distractions make understanding and remembering instructions challenging to patients. Since these other factors cannot be eliminated at the time of discharge, researchers and clinicians explore different strategies to make the instructions easier to understand. There have been a few studies showing that the addition of pictures can enhance the comprehension of written medical instructions [19]. In a study by Austin et al, comprehension of discharge instructions increased by 1.5 times when pictures were added to the instructions [14]. Mansoor and Dowse [15] reported that comprehension of the correct method for taking a medicine increased from 47% to 93% when pictures were added. The authors also reported that comprehension of the proper times to take a medicine increased from 3% to 73% when pictures were added. The effects of pictures on recall are less conclusive. There have been studies that show no effect [16] as well as studies that show an increase in recall when pictures are added to written instructions [17,18].

While studies have demonstrated that pictographs can improve comprehension, several factors inhibit the use of pictographs in discharge instructions. There exists no standard pictographic language for patient communication, and there has been limited research on how to systematically develop and evaluate pictographs for patient communication. In an attempt to foster the use of pictographs, we are conducting a three-stage project on systematic ways to develop pictographs that are effective for patient communication. In the first stage, we experimented with a participatory design process. In the second and current stage, we assessed the recognition of individual pictographs that were developed by us using a well-established pictographic system as a reference point. In the third stage, we will analyze which syntactic and semantic factors are the best predictors of pictographic recognition. The analysis also involves the identification of the best representation techniques for each category of concept.

Prior Work

In one of our previous studies, we used a participatory design process to design pictographs to improve comprehension and recall of discharge instructions [20]. We recruited four participants—two nurses and two consumers—to identify discharge instructions that could be improved through pictorial aids and to help design the pictographs. The participants were presented with 38 specific instructions selected from a convenience sample of 30 discharge documents. For each instruction, the participant was asked to consider the following: (1) Is the instruction easy to understand? (2) Will the use of a pictograph make the instruction easier? (3) If a pictograph is recommended, what is the best way to design it?

The nurses suggested that 32 of the 38 instructions would benefit from a pictograph and provided specific instructions for their design. The consumers did not identify any specific instruction, but they believed that, in general, including a pictograph would be helpful.

Due to time and resource constraints, we selected 20 of the 32 instructions as candidates for pictograph design. The initial designs were developed by one investigator in our group and given to the nurses and consumers for review and feedback. Participants were asked to consider whether the meaning of the pictograph was clear, whether the label matched the semantics, and how (if) the pictograph could be improved.

To evaluate the pictographs, we composed two mock-up discharge instruction documents, A and B, based on two different medical scenarios. For each mock-up we created two versions: a text-only version reflecting a typical discharge instruction sheet and a pictograph-enhanced version using the images we developed. The mock-up documents were tested on a convenience sample of 13 subjects. Each subject was randomly assigned to one of two groups. Group I received the text version of A and the pictograph-enhanced version of B. Group II received the text version of B and the pictograph-enhanced version of A.

In evaluation, each participant was presented with an instruction and was asked to assume the role of a patient being discharged while the investigator played the role of a discharge nurse. Immediate recall was measured by asking the participant to write down what he or she remembered immediately after reading and reviewing the instruction. Delayed recall was collected, also in writing, after 5 days. The same procedure was used for the second instruction. The correctness of participants' answers was not conditional to verbatim recall. If the original instruction was "avoid swimming" and a participant wrote "do not swim," that item would be scored as correct. Each item in the participants' responses was scored as correct, partially correct, or wrong. For example, if a participant wrote down "take this drug two hours before eating dairy food" and the original instruction was "take this drug two hours before or two hours after eating dairy food," that item would receive a partial score. The interviewing nurse was responsible for rating the correctness and completeness of each recalled instruction.

Both immediate and delayed recall rates were higher for the pictograph-enhanced instruction. The mean immediate recall rates were 44.28% (sd16.14%) for the text-only version and 53.51% (sd17.53%) for the pictograph-enhanced condition. The mean delayed recall rates (5 days) were 27.31% (sd14.09%) for the text-only condition and 33.03% (sd15.95%) for the pictograph-enhanced condition. Mixed factor linear regression analysis found statistically significant effects ($P < .001$) of presentation format (text versus text and pictograph) on the recall rate. The effect of case (A or B) on the recall rate was not significant ($P = .49$). The results suggested that the pictographs we developed were effective in improving the recall of discharge instructions. These results are consistent with existing research. Kitching found that outpatients usually forget about 50% of their doctor's instructions within 5 minutes of leaving the doctor's office [21]. In another study, by Logan et al, only 37% of patients could correctly recall their diagnosis, treatment, and follow-up plans immediately after being discharged from the emergency room [22].

Objectives

Although the pictographs in the study described above were developed through a participatory design process and were shown to improve instruction recall, we considered it important to conduct further studies to assess the individual pictographs. Pictographs used in health care are often empirically designed and seldom quantitatively evaluated [23]. Without a systematic design approach, pictographs are less likely to be useful or helpful. For example, Hwang et al reported that the addition of a certain set of icons did not improve patients' comprehension of medication labels [5]. Rigorous and quantitative evaluations are needed because user preference alone is not a reliable measure of the effectiveness of pictographic communication [23].

The main objective of this study was to verify the recognition of individual pictographs created through a participatory design process. We hypothesized that comprehension and recognition would be affected by the individual characteristics of the pictographs as well as by the characteristics of the intended audience (demographic factors).

Methods

Materials

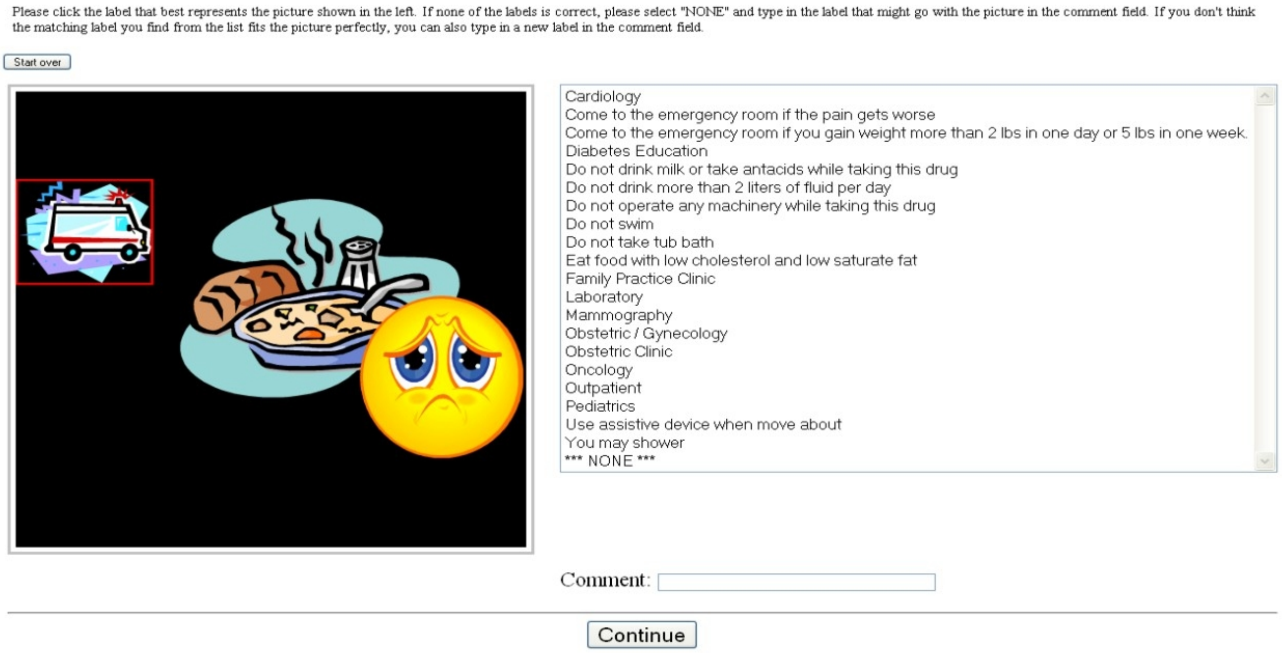
In this study, we included 20 pictographs developed by our research group in a prior study and 20 pictographs developed by the Hablamos Juntos project, funded by the Robert Wood Johnson Foundation (RWJF) [24]. It is important to emphasize that we are not using the RWJF pictographs for direct comparison but rather as a reference point for pictographic recognition. The two pictographic systems are indeed very different in nature. The RWJF pictographs were designed to help visitors navigate health facilities, whereas our pictographs were designed to help patients understand discharge instructions. Wayfinding pictographs, like traffic signs, are supposed to be graphically as simple as possible. Pictographs depicting medical instructions are necessarily more elaborate as the messages they are supposed to convey are far more complex. We chose the RWJF pictographs as a comparison reference because they are one of the most successful examples in the health care domain, where systematic initiatives in pictographic communication are few. See the Multimedia Appendix for the complete list of pictographs.

Each participant was asked to identify 10 pictographs developed by our group and 10 pictographs developed by RWJF. The pictographs developed in-house were color images, whereas those collected from RWJF were black-and-white.

To assess whether the participants could recognize the meaning of the pictographs, we designed an asymmetrical pictograph–text label-linking test. For each pictograph, we provided 20 labels. The correct label for the pictograph was presented among the 20 labels 70% of the time. The order of the pictographs and the text labels was randomized. The participants were asked to select either a matching label or "none" if no label appeared to match. Thus, if a participant made random selections, there would be less than a 5% chance of getting the right answer. On the other hand, since recognition is an easier cognitive task than recall, this is not an overly challenging task. When the participant picked the "none" option, he or she was given the opportunity to suggest an accurate label, although suggesting a new label was not required.

To facilitate the anonymous survey study, we created a Web-based tool. A screenshot of the survey tool is shown in Figure 1. No adaptive questioning procedures were used. We did not perform consistency or completeness checks before the questionnaire was distributed.

Figure 1. Screenshot of the Web-based survey tool for pictograph evaluation



Please click the label that best represents the picture shown in the left. If none of the labels is correct, please select "NONE" and type in the label that might go with the picture in the comment field. If you don't think the matching label you find from the list fits the picture perfectly, you can also type in a new label in the comment field.

Cardiology
Come to the emergency room if the pain gets worse
Come to the emergency room if you gain weight more than 2 lbs in one day or 5 lbs in one week.
Diabetes Education
Do not drink milk or take antacids while taking this drug
Do not drink more than 2 liters of fluid per day
Do not operate any machinery while taking this drug
Do not swim
Do not take tub bath
Eat food with low cholesterol and low saturate fat
Family Practice Clinic
Laboratory
Mammography
Obstetric / Gynecology
Obstetric Clinic
Oncology
Outpatient
Pediatrics
Use assistive device when move about
You may shower
*** NONE ***

Sampling

We worked with a convenience sample. After obtaining approval from the Institutional Review Board, the survey was advertised via email to colleagues and acquaintances of the authors. Participation was voluntary and anonymous. No monetary or non-monetary incentives were offered. To evaluate the effects of demographic factors on the perception of pictographs, the survey also asked six demographic questions about age bracket, race, ethnicity, education level, and the continent where the participant grew up.

Analysis

The participants' answers were scored according to whether they were correct or not. The scores were also weighted to reflect the difficulty of providing a correct answer, depending on the presence or absence of a correct label (Table 1). "Correct label selected" involves scanning the list; it is a self-terminating search (weight: 1). "None selected" requires the subject to serially review the list; it is an exhaustive search—all items need to be considered (weight: 2). "Correct term added" requires the spontaneous generation of an appropriate label (weight: 3).

Table 1. Scoring scheme for the label-linking test (weights are in parentheses)

	Actual Label Present	Actual Label Absent
Correct label selected	1 (1)	N/A
Incorrect label selected	0 (1)	0 (1)
None selected, correct term not added	0 (1)	1 (2)
None selected, correct term added	N/A	1 (3)

We calculated weighted average scores for every pictograph, for the different demographic groups, and for the two pictograph sources (those developed in-house versus those developed by RWJF). In addition, we used the Wilcoxon two-sample test to examine the effect of demographic factors on recognition of the pictographs. For some demographic variables, several small categories were collapsed into one group, and the cases with missing demographic information were omitted from the analysis.

Results

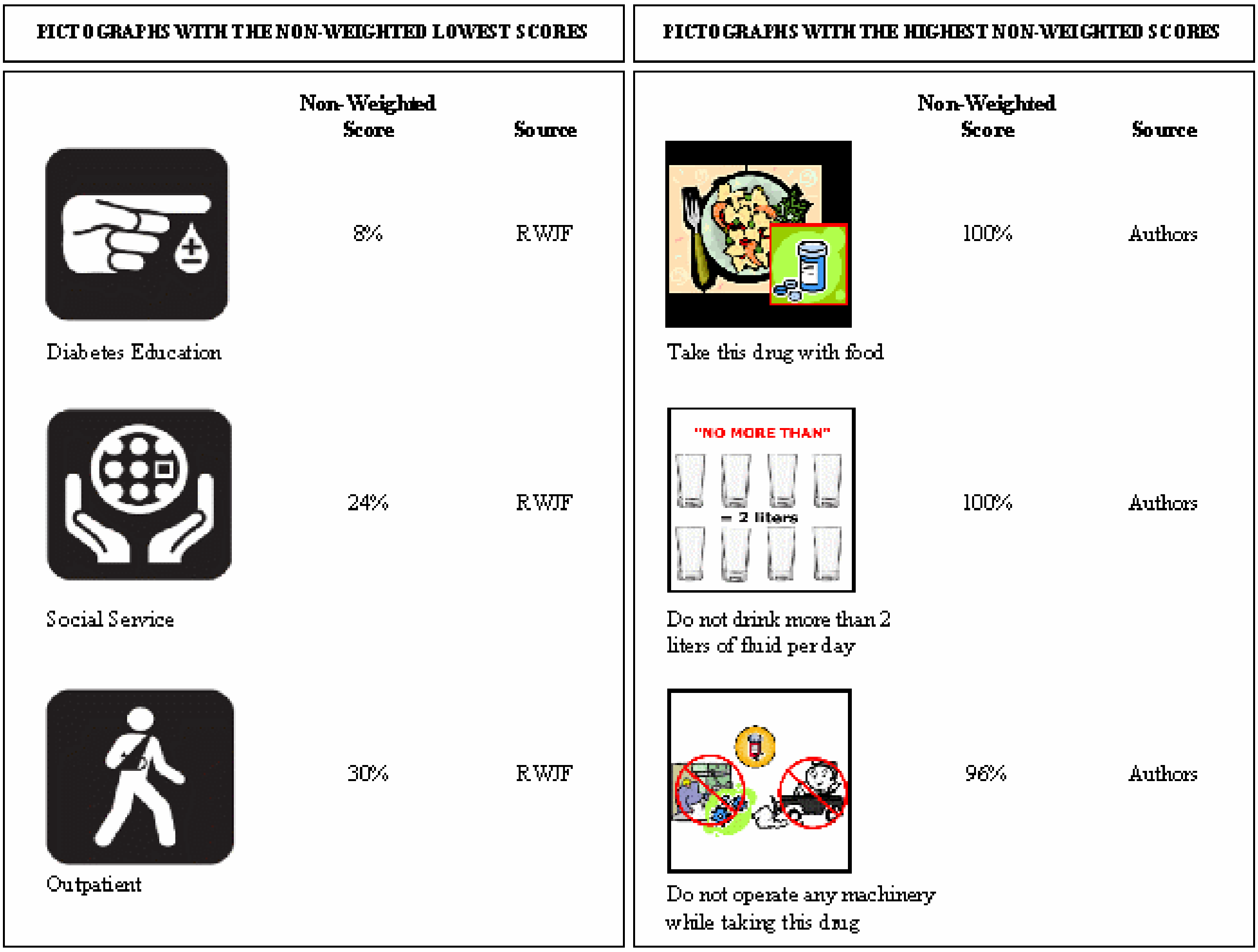
Survey data were collected for the 7 days following the email invitation. A total of 44 people accessed the survey site. We excluded 7 participants who completed less than 50% of the survey. A total of 719 answers from 37 participants were used for the analysis. The number of answers obtained per pictograph varied from 11 to 25 due to incomplete survey sessions. The majority of the study participants were highly educated, Caucasian men between 18 and 39 years old who grew up in North America, Asia, or Europe (Table 2).

Table 2. Demographic characteristics of the survey participants

Demographic Characteristic	No.	Percent
Gender		
Male	22	60
Female	13	35
Unknown	2	5
Age		
18-29	14	38
30-39	14	38
40-49	4	11
50-59	3	8
Unknown	2	5
Race		
Asian	11	30
Caucasian	21	57
Other	1	2
Unknown	4	11
Ethnicity		
Hispanic	3	8
Non-Hispanic	30	81
Unknown	4	11
Education		
College, vocational school	1	3
University	3	8
Graduate school	31	84
Unknown	2	5
Continent Grew Up In		
Asia	10	27
Europe	8	22
Middle or South America	2	5
North America	12	32
Unknown	5	14

The majority of the pictographs were recognized by most participants. The average weighted recognition score was 71.81% for the pictographs developed in-house and 57.27% for the RWJF pictographs. However, 7 out of the 40 pictographs obtained scores below 50%; 2 were developed in-house and the other 5 were developed by RWJF. Non-weighted scores measure how successful the participants were in the linking task. Weighted scores take into consideration whether or not participants were able to infer the meaning of the pictographs in cases where the correct label was not present in the list. None of the pictographs received a perfect weighted score. However, 2 of the pictographs developed in-house (“Take this drug with food” and “Do not drink more than 2 liters of fluid per day”) were successfully connected to the right label (or the “none” option) by all participants. The 3 pictographs with the highest and the 3 pictographs with the lowest non-weighted scores are presented in Figure 2.

Figure 2. Pictographs with the lowest and highest recognition scores



PICTOGRAPHS WITH THE NON-WEIGHTED LOWEST SCORES

	Non-Weighted Score	Source
Diabetes Education	8%	RWJF
Social Service	24%	RWJF
Outpatient	30%	RWJF

PICTOGRAPHS WITH THE HIGHEST NON-WEIGHTED SCORES

	Non-Weighted Score	Source
Take this drug with food	100%	Authors
Do not drink more than 2 liters of fluid per day	100%	Authors
Do not operate any machinery while taking this drug	96%	Authors

The weighted average scores were calculated and compared by demographic groups and pictograph source (Table 3). The analysis showed that the participants recognized the pictographs developed by the authors significantly better than those developed by RWJF (*P*< .001). This trend was true regardless of the participant's gender, age, and education level. However, this trend did not hold for non-Caucasian groups. The weighted average score did not show statistically significant differences between genders, age groups, ethnicities, and education levels, which may be partially attributed to the small number of participants in some demographic groups.

Table 3. Weighted recognition scores by demographics and sources

	All	By Source		*P* [a]
		Authors	RWJF	
All (n = 37)	.80	.87	.73	< .001[b]
Gender (n = 33)				
Female	.78	.86	.70	< .001[b]
Male	.82	.88	.76	.006[b]
P value	.52	.74	.41	
Age (n = 35)				
< 40	.81	.87	.74	.001[b]
≥ 40	.80	.89	.71	.006[b]
P value	.93	.79	.67	
Race (n = 33)				
Non-White	.69	.76	.63	.07
White	.87	.93	.80	< .001[b]
P value	.004[b]	.003[b]	.03[b]	
Ethnicity (n = 33)				
Hispanic	.92	.97	.86	[c]
Non-Hispanic	.79	.86	.73	< .001[b]
P value	[c]	[c]	[c]	
Education (n = 35)				
Less than graduate school	.76	.83	.68	[c]
Graduate school	.81	.88	.74	< .001[b]
P value	[c]	[c]	[c]	
Place Grew Up In (n = 32)				
Other than North America	.75	.82	.68	.002[b]
North America	.88	.93	.83	.03[b]
P value	.04[b]	.07	.06	

[a] Tested between the sources.

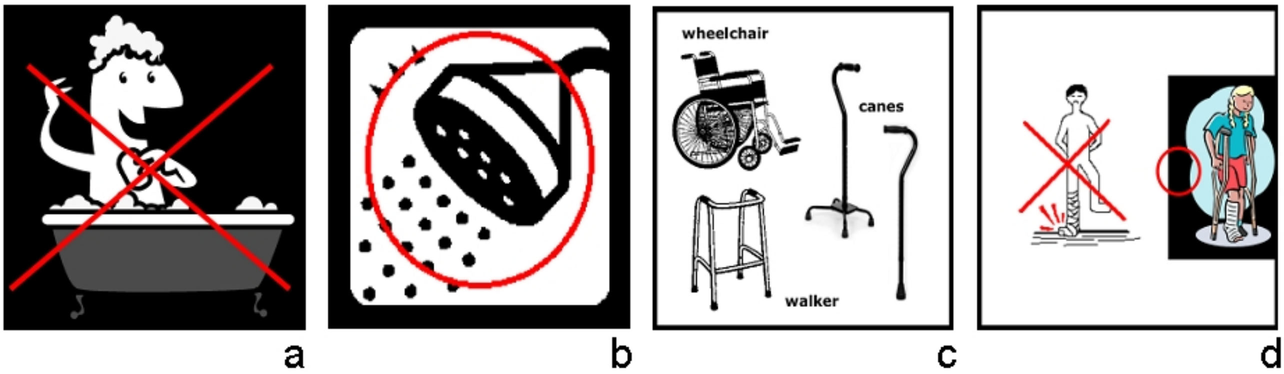
[b] The mean differences are significant at 95% significance level.

[c] Statistical tests were not conducted due to large differences between group sizes.

Recognition of Individual Pictographs in Relation to Underlying Concepts and Representation Strategies

We made a few observations when analyzing the recognition rate of individual pictographs in relation to their underlying concepts and representation strategies. Most notably, the recognition of pictographs tended to decrease when a person is not included in the picture. For example, 19 out of 22 participants (86%) were able to tell whether the correct label was present or not in the linking test for the “Do not take tub bath” instruction, which included a person in the tub. However, only 6 out of 11 participants (55%) were able to do so with the instruction “You may shower,” which depicted only the shower but no person (see Figure 3). Similarly, 13 out of 17 participants (76%) successfully completed the linking test for the instruction “Do not put your weight on your wounded leg,” whereas 10 out of 15 participants (67%) were successful with the instruction “Use assistive device when moving about,” which did not include any person. These results are consistent with prior research showing that people prefer pictures that include people like themselves [25]. Moreover, the depiction of isolated objects may fail to convey the concept of a verb, which is essential for the comprehension of an instruction.

Figure 3. (a) Do not take tub bath; (b) You may shower; (c) Use assistive device when moving about; (d) Do not put your weight on your wounded leg



Another observation is that "presence" is easier to represent and understand than "absence." Take the examples of the pictographs representing "Take this drug with food" and "Take this drug on an empty stomach" (see Figure 4). The former can be easily represented by any depiction of a meal, examples of food, etc. The latter representation is more challenging, so much so that the designer resorted to the use of words to convey the concept of "emptiness." All 25 participants (100%) successfully completed the linking part of the test for the former, whereas 21 out of 25 participants (83%) did so for the latter. Even with the addition of a verbal descriptor, the concept of "emptiness" was less recognizable than its counterpart.

Figure 4. (a) Take this drug with food; (b) Take this drug on an empty stomach

A third observation is that abstract concepts are very difficult to represent and understand without the use of some conventions (most notably, words). Take the example of the pictographs "Come to the emergency room if the pain gets worse" and "Come to the emergency room if you cannot eat food" (see Figure 5). In the first example, the pictograph was complemented by the word "pain." In the second, the reader must infer the idea of an "eating difficulty" without any verbal support. For the former, 9 out of 12 participants (75%) successfully completed the linking part of the test for the meaning of the pictograph, whereas 9 out of 14 participants (63%) did so for the meaning of the latter. It is important to emphasize here that the inclusion of words in pictographs may be less helpful for audiences with poor reading skills. It can be even detrimental if the final audience cannot read English at all. Thus, the inclusion of words in pictographs has to be carefully considered against the assumed reading skills of the intended audience.

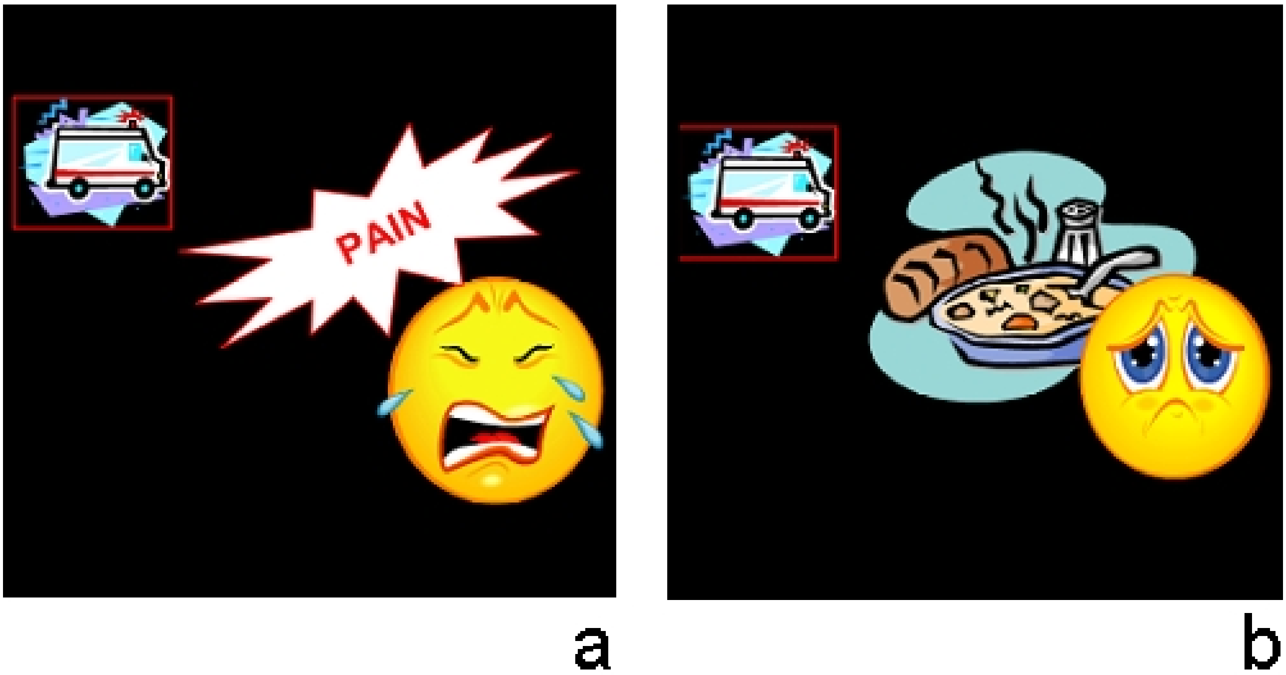


Figure 5. (a) Come to the emergency room if the pain gets worse; (b) Come to the emergency room if you cannot eat food

Discussion

Principal Results

This study confirmed that the majority of the pictographs developed in a participatory design process involving a small number of nurses and consumers were recognizable by a much larger number of consumers. Because RWJF pictographs and our pictographs differ in content and color scheme, a direct comparison between the two is not warranted. However, the RWJF pictographs have been evaluated by over 300 multilingual testers from four language groups [23]. The average recognition score of RWJF pictographs provides a reference point in evaluating the pictographs we developed.

The results also revealed that there is a large variance in the quality of the pictographs developed using the same design process—the recognition rate ranged from below 50% to above 90%. This suggests that pictographs should be assessed individually before being evaluated within the context of an application. Even with the limited number of participants in this study, we observed statistically significant effects of some demographic variables on the recognition of certain pictographs. We thus conclude that assessment tests should always be conducted to ensure that the pictographs used to enhance discharge instructions are appropriate for a diverse patient population.

Both theoretical and empirical studies indicate that the interpretation of pictures is culturally mediated [25-27]. That is, pictures are not universally understood. They carry many cultural components that affect their interpretation. The break down of our results by demographic factors is consistent with those studies. The only differences that were statistically significant were race and continent of origin. Both factors are strongly related to cultural differences. Although education has also been identified as an important factor, we could not analyze it statistically due to large differences between group sizes.

Limitations

Given our small sample size, we worked with less than optimal statistical power to detect differences in comprehension among the demographic groups. Furthermore, participants in this study were mostly highly literate people. Therefore, we would expect some variation in the ratio of comprehension for populations with much lower literacy levels, which are the people who would benefit the most from the use of pictorial communication.

Because the online survey involved recognition rather than recall, we were not able to capture the potential variations in the interpretation of the pictographs that people may have. Because visual communication is intrinsically less coded than verbal communication, it may often fail to convey certain linguistic intricacies. For example, a pictograph meant to express the warning “Do not take this drug with milk or antacid” could as well be interpreted as “Do not drink milk or antacid while taking this drug.” However, since the pictographs are supposed to complement rather than replace written text, this would not invalidate the relevance of our results.

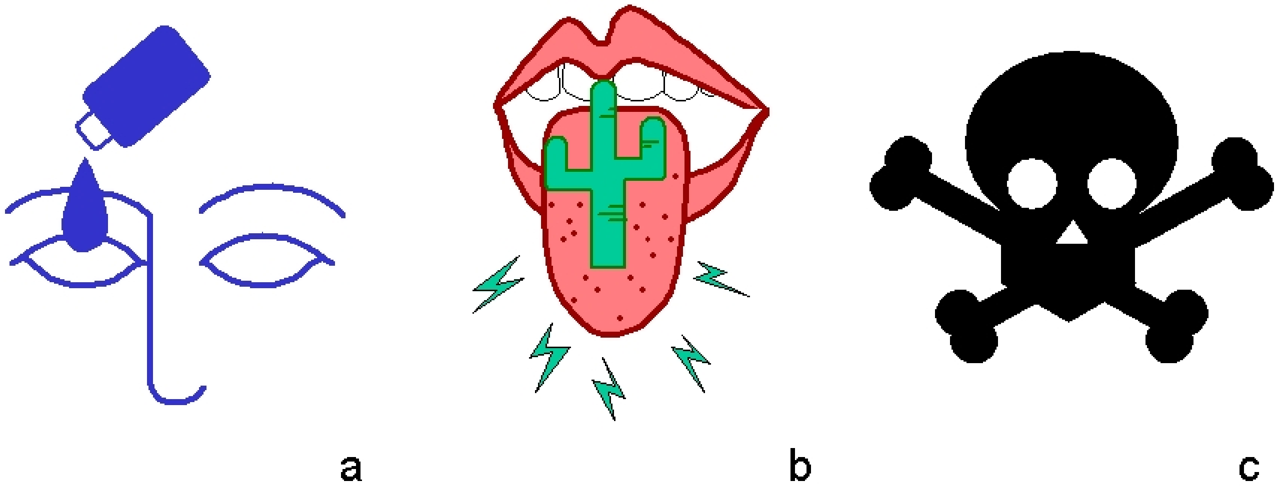
We have made some observations on the recognition of individual pictographs in relation to their underlying concepts and representation strategies. These observations are still preliminary at this point. More in-depth analyses involving larger samples are indeed necessary. Such analyses are currently being conducted by our research group but are still incipient to be presented here. More information on our follow-up work is offered in the next section.

Future Directions

In regard to sampling procedures, future studies will achieve more robust outcomes by focusing on more representative and vulnerable populations. Existing research has shown that the vulnerable or at-risk groups are those with less than a high school education, those with racial/ethnic minority status, and those who are over the age of 65 [28].

In regard to the relative recognition levels of the pictographic system we are developing, the results of this study were encouraging. However, they do not quite answer the question of what makes a pictograph easier or harder to understand. To address that concern, we have started the third stage of our project in which we analyze the degree to which pictographs match the concepts they are supposed to depict. This is a taxonomical study in which we adapt discourse analysis techniques to classify pictographs according to their syntactic and semantic design principles. Based on our preliminary analyses, we have found, for instance, that pictographs can relate to concepts by visual similarity, semantic association, or convention (see Figure 6). Pictographs created by similarity tend to be easier to interpret because they actually resemble the concept being depicted. Pictographs developed through semantic association are less reliable because their interpretation depends on the identification of what kind of analogy is being employed (as in the case of a picture of a cactus on a tongue to indicate “dry mouth”). Pictographs that relate to a concept by convention represent a trade-off: those familiar with the convention being used can understand the pictograph instantly, whereas those who are unfamiliar will probably not understand the pictograph at all (as in the case of a skull indicating “poison”). Pictographs created by convention are, thus, the least robust against cultural differences. This is just one example of the many forms of categorization we are employing to produce a taxonomic model that will help us predict the relative recognition of individual pictographs.

Figure 6. (a) Example of composition by visual similarity: eye drops; (b) Example of composition by semantic association: dry mouth; (c) Example of composition by convention: poison



Acknowledgments

The authors thank the study participants. This work is supported by the NIH grant R01 LM07222, R01 DK75837.

Conflicts of Interest

None declared.

Multimedia Appendix

Pictographs used in the study

[PDF file(Adobe PDF), 565KB - jmir_v11i1e4_app1.pdf]

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Abbreviations

CMS: Centers for Medicare and Medicaid Services
JCAHO: Joint Commission on Accreditation of Healthcare Organizations
RWJF: Robert Wood Johnson Foundation

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Original Paper

A Virtual Clinic for Diabetes Self-Management: Pilot Study

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Abstract

Background: Internet-based interventions to assist in diabetes management have the potential to provide patients with the information and support they need to become effective self-managers.

Objective: To assess the feasibility, acceptability, and effectiveness of an Internet-based virtual clinic designed to facilitate self-management in patients who used insulin pumps to manage their diabetes.

Methods: For a period of 6 months, 17 patients joined the virtual clinic. The system allowed patients to communicate with health professionals, interact with peers and access information. HbA1c, quality of life, and self-efficacy were monitored at baseline and after 6 months. Questionnaires and qualitative interviews examined patient experiences.

Results: Participants found the virtual clinic easy to use and positively rated its design. Peer support was the most valued aspect and the discussion boards the most used component. All participants highly rated the virtual clinic in terms of improving communication with peers, but few agreed it had improved communication with health care professionals. No significant improvements in physiological and psychological measurements were found. Regarding HbA1c measurements, there was no significant difference found between the pre- and post-test results ($P = .53$). Mean ADDQoL scores at baseline were -2.1 (SD 1.1, range -3.4 to -0.5) compared to -2.0 (SD 1.2, range, -4.6 to -0.4) post-test ($n = 12$), ($P = .62$). Surprisingly, patients' confidence in their ability to perform self-care tasks was found to be significantly reduced from baseline to follow up ($P = .045$).

Conclusions: An Internet-based system to aid the management of diabetes appears feasible and well accepted by patients. The pilot study did not identify evidence of an impact on improving quality of life or self-efficacy in patients who used insulin pump therapy.

(J Med Internet Res 2009;11(1):e10) doi:10.2196/jmir.1111

KEYWORDS

Internet; diabetes mellitus; intervention studies; virtual systems; self-efficacy

Introduction

The Diabetes Control and Complications Trial has conclusively shown that effective control of blood glucose levels delays the onset and slows the progression of diabetes complications [1]. The day-to-day management of diabetes is carried out almost exclusively by the patient and can often be complex and emotionally challenging. To enable patients to be effective self-managers of their diabetes, they need to be provided with the information and support necessary to make informed decisions [2]. Internet-based interventions to aid self-management have the potential to assist patients by offering access to these resources from their own homes, schools, or workplaces and at times when they are most in need of them.

A number of recent Internet-based interventions have been reported on for use with patients with diabetes [3-10], and a pilot study has shown the feasibility of patients with type 2 diabetes co-managing their condition from home [11]. Most of the studies have assessed the usage or usability of their telemedicine systems [3-6,8-11]; some have assessed biological measures, namely HbA1c [3-5,7,9,11]; and one has reported on psychological measurements [5]. Results often indicate improvements in HbA1c values but limited improvements in psychological measurements. Many of the systems have shown feasibility and potential benefits for improvement of diabetes care.

The systems developed for these interventions were often based on the uploading of biological measurements, whilst others provided patients with access to online self-management "coaches". As a result, these interventions have commonly used complex and bespoke systems; few have used freely available communities. In order for an Internet-based system to be effective, it needs to employ a simple user interface to collect a minimum amount of data [12]. In the current study, a pre-existing virtual clinic prototype was developed as an intervention to aid diabetes self-management, one aimed at patients who used insulin pumps to manage their diabetes.

Continuous subcutaneous insulin infusion (CSII), or pump therapy, is a method of administering insulin over twenty-four hours via a small needle or cannula inserted under the skin. The pump delivers insulin continuously with an additional boost programmed and administered by the patient to match food or reduce raised blood glucose levels [13]. There are a number of reasons why patients may be recommended for CSII. These include inadequate glycemic control with other treatment options, marked variability in glucose on a day-to-day basis, a history of hyperglycemia unawareness, a need for flexibility in lifestyle, pregnancy, insulin sensitivity and low insulin requirements [14]. This particular group has not been studied in any of the previous interventions referenced, despite insulin pump patients showing a great deal of interest in their condition and motivation towards self-management [15].

Community support is believed to be a fundamental aspect of disease self-management, and when peer-support elements are incorporated into Internet-based interventions for diabetes, they are often the most used components [5,10]. The benefits of peer support in relation to health include: decreased feelings of isolation, promotion of positive psychological states and increased motivation, deterring maladaptive behaviors, and providing information on the benefits of behaviors that positively influence health [16]. Studies have shown that discussion forums and chat rooms can have a positive effect on participants by helping them to cope better with diabetes [17].

Self-efficacy can also increase the successful self-management of diabetes. The theory of self-efficacy proposes that an individual's confidence in their ability to perform a certain behavior influences which behavior they will engage in, how much effort will be expended, and how long they will persist in it [18]. Interventions based on self-efficacy theory have been shown to be significantly more effective than those that are not [19].

In addition to ensuring that the content of an intervention increases self-efficacy, it is important that a system meets patient needs and is designed in conjunction with potential users. Hence, extensive stakeholder consultation [20] and preliminary testing [21] were undertaken to ensure public and patient involvement at all stages of the system's development. Following this patient-centered approach, we report here on pilot testing of the Internet-based virtual clinic for patients using insulin pumps to manage their diabetes. We aimed to explore the feasibility, acceptability, and effectiveness of the system.

Methods

System Design

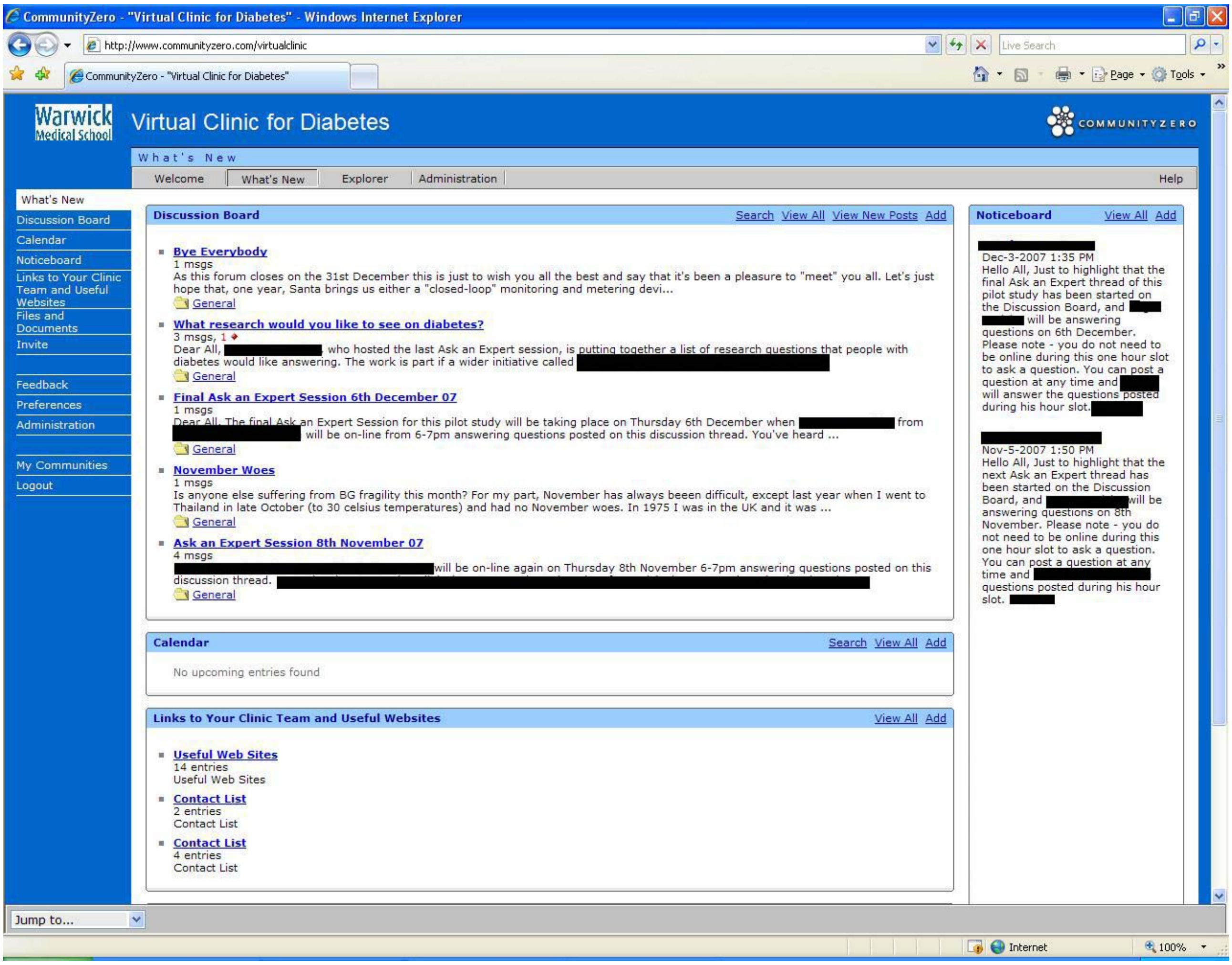
The virtual clinic system offered three main Internet-based functions: communication with health professionals, interaction with peers, and access to information (Figure 1 and Figure 2). The site was password protected and only available to the participants involved and those working directly on the study.

Communication with health professionals was provided via 6 online "ask an expert" sessions conducted with diabetes specialists not directly involved with the patients care. These sessions were conducted via the sites asynchronous discussion forums which were open to all who could access the site. Participants were also able to confidentially email their own health professionals at any time and were told to expect a reply within two working days. Interaction with peers was provided via discussion boards and synchronous chat. Discussion board moderation was reactive in that the boards were checked regularly by the study coordinator, and participants were encouraged to report any inappropriate postings. Information on diabetes was provided on the site and via Web links to further sources, including Diabetes UK [22] and sites specific to patients using insulin pumps such as Pumpers UK [23] and Promoting Insulin Pump Therapy (INPUT) [24].

Sample

Participants were recruited by convenience sampling from three UK hospitals in the West and East Midlands. As the sample was drawn on the basis of opportunity, recruitment was convenient and not time consuming; however, it did increase the risk of bias and the possibility of obtaining a non-representative sample.

Figure 1. Screenshots of the virtual clinic: homepage



Discussion Board Search View All View New Posts Add

- **Bye Everybody**
  1 msgs
  As this forum closes on the 31st December this is just to wish you all the best and say that it's been a pleasure to "meet" you all. Let's just hope that, one year, Santa brings us either a "closed-loop" monitoring and metering devi...
  General
- **What research would you like to see on diabetes?**
  3 msgs, 1 ◆
  Dear All, [redacted] who hosted the last Ask an Expert session, is putting together a list of research questions that people with diabetes would like answering. The work is part if a wider initiative called [redacted]
  General
- **Final Ask an Expert Session 6th December 07**
  1 msgs
  Dear All, The final Ask an Expert Session for this pilot study will be taking place on Thursday 6th December when [redacted] from [redacted] will be on-line from 6-7pm answering questions posted on this discussion thread. You've heard ...
  General
- **November Woes**
  1 msgs
  Is anyone else suffering from BG fragility this month? For my part, November has always beeen difficult, except last year when I went to Thailand in late October (to 30 celsius temperatures) and had no November woes. In 1975 I was in the UK and it was ...
  General
- **Ask an Expert Session 8th November 07**
  4 msgs
  [redacted] will be on-line again on Thursday 8th November 6-7pm answering questions posted on this discussion thread. [redacted]
  General

Calendar Search View All Add

No upcoming entries found

Links to Your Clinic Team and Useful Websites View All Add

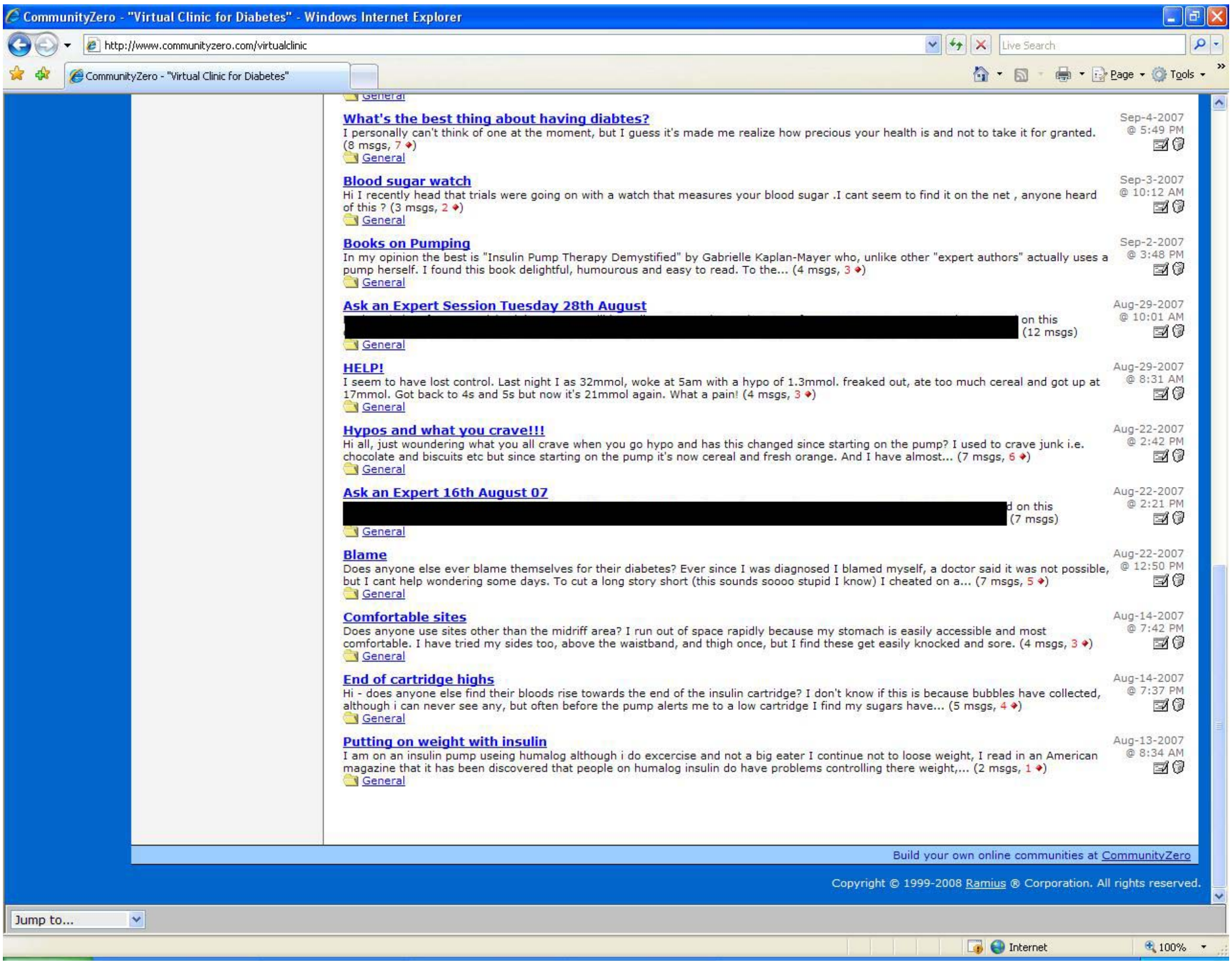
- **Useful Web Sites**
  14 entries
  Useful Web Sites
- **Contact List**
  2 entries
  Contact List
- **Contact List**
  4 entries
  Contact List

Noticeboard View All Add

[redacted]
Dec-3-2007 1:35 PM
Hello All, Just to highlight that the final Ask an Expert thread of this pilot study has been started on the Discussion Board, and [redacted] will be answering questions on 6th December. Please note - you do not need to be online during this one hour slot to ask a question. You can post a question at any time and [redacted] will answer the questions posted during his hour slot. [redacted]

[redacted]
Nov-5-2007 1:50 PM
Hello All, Just to highlight that the next Ask an Expert thread has been started on the Discussion Board, and [redacted] will be answering questions on 8th November. Please note - you do not need to be online during this one hour slot to ask a question. You can post a question at any time and [redacted] questions posted during his hour slot. [redacted]

Figure 2. Screenshots of the virtual clinic: discussion forum



General

What's the best thing about having diabtes?
I personally can't think of one at the moment, but I guess it's made me realize how precious your health is and not to take it for granted. (8 msgs, 7 ◆)
General
Sep-4-2007 @ 5:49 PM

Blood sugar watch
Hi I recently head that trials were going on with a watch that measures your blood sugar .I cant seem to find it on the net , anyone heard of this ? (3 msgs, 2 ◆)
General
Sep-3-2007 @ 10:12 AM

Books on Pumping
In my opinion the best is "Insulin Pump Therapy Demystified" by Gabrielle Kaplan-Mayer who, unlike other "expert authors" actually uses a pump herself. I found this book delightful, humourous and easy to read. To the... (4 msgs, 3 ◆)
General
Sep-2-2007 @ 3:48 PM

Ask an Expert Session Tuesday 28th August
[redacted] on this (12 msgs)
General
Aug-29-2007 @ 10:01 AM

HELP!
I seem to have lost control. Last night I as 32mmol, woke at 5am with a hypo of 1.3mmol. freaked out, ate too much cereal and got up at 17mmol. Got back to 4s and 5s but now it's 21mmol again. What a pain! (4 msgs, 3 ◆)
General
Aug-29-2007 @ 8:31 AM

Hypos and what you crave!!!
Hi all, just woundering what you all crave when you go hypo and has this changed since starting on the pump? I used to crave junk i.e. chocolate and biscuits etc but since starting on the pump it's now cereal and fresh orange. And I have almost... (7 msgs, 6 ◆)
General
Aug-22-2007 @ 2:42 PM

Ask an Expert 16th August 07
[redacted]d on this (7 msgs)
General
Aug-22-2007 @ 2:21 PM

Blame
Does anyone else ever blame themselves for their diabetes? Ever since I was diagnosed I blamed myself, a doctor said it was not possible, but I cant help wondering some days. To cut a long story short (this sounds soooo stupid I know) I cheated on a... (7 msgs, 5 ◆)
General
Aug-22-2007 @ 12:50 PM

Comfortable sites
Does anyone use sites other than the midriff area? I run out of space rapidly because my stomach is easily accessible and most comfortable. I have tried my sides too, above the waistband, and thigh once, but I find these get easily knocked and sore. (4 msgs, 3 ◆)
General
Aug-14-2007 @ 7:42 PM

End of cartridge highs
Hi - does anyone else find their bloods rise towards the end of the insulin cartridge? I don't know if this is because bubbles have collected, although i can never see any, but often before the pump alerts me to a low cartridge I find my sugars have... (5 msgs, 4 ◆)
General
Aug-14-2007 @ 7:37 PM

Putting on weight with insulin
I am on an insulin pump useing humalog although i do excercise and not a big eater I continue not to loose weight, I read in an American magazine that it has been discovered that people on humalog insulin do have problems controlling there weight,... (2 msgs, 1 ◆)
General
Aug-13-2007 @ 8:34 AM

Build your own online communities at CommunityZero

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Clinicians issued recruitment packs, which consisted of a letter inviting patients to participate and an information sheet outlining the research, to all patients in their diabetes clinics who currently used insulin pumps. Patients were informed that participation was voluntary and refusing participation or withdrawing from the study would not affect their current standard of care. Ethical approval for the study was obtained from the West Midlands Multi-Centre Ethics Committee.

All the participants were over 18 years of age, had used an insulin pump for at least 6 months, could communicate effectively in written and spoken English, had Internet access, and self-reported basic computer literacy. While still receiving normal care, participants were asked to use the virtual clinic for a period of 6 months, logging on at least once a week and using the features within it as often as they wished.

Measures

The feasibility of the virtual clinic system was determined from recruitment, retention, and usage rates; acceptability was monitored by participant evaluation and informal feedback; and effectiveness was measured by a comparison of pre- and post-test results. Outcome measures were selected following a review of similar studies in this area. As this was a pilot study, it was important to choose measures that would provide feedback in a range of areas, including psychological and physiological. This allowed for a thorough assessment of the intervention and its impact on participants.

Demographic information was recorded using a self-report questionnaire at baseline. Pre-study HbA1c values were obtained, with permission, from patients' files. Self-efficacy was assessed by the Confidence in Diabetes Self-Care Scale (CIDS) [25] and quality of life by the Audit of Diabetes Dependent Quality of Life (ADDQoL) questionnaire [26]. Participants completed questionnaires by hand and returned them by post.

The CIDS scale is a 21-item self-report questionnaire that covers domains of self-care (eg, insulin administration and blood glucose monitoring). The scale was developed to assess self-efficacy, specifically in adults with type 1 diabetes. Its advantages are that it is a short instrument that has shown high reliability and validity. Respondents are required to score items on a five-point Likert scale from 1 ("No, I am sure I cannot") to 5 ("Yes, I am sure I can"). A total score is then calculated by summing all items and converting them to a 0-100 scale, with higher scores indicating higher self-efficacy [25].

The ADDQoL questionnaire measures patients' perceptions of the impact of diabetes on their quality of life with the underlying principle that only personally applicable domains are rated by respondents. The questionnaire consists of 18 life domains (eg, family life, employment, and holidays), and users rate the impact of diabetes on each particular domain and the importance of that domain for their quality of life. A score of +9 is the maximum positive impact of diabetes and -9 the maximum negative impact of diabetes [26]. The advantage of using the ADDQoL questionnaire is that, unlike other quality of life measures that only assess patients' satisfaction with treatment, a broader range of topics influenced by diabetes, its treatment, and any complications are covered. Furthermore, the questionnaire allows patients to rate only those areas of life that are important to their quality of life.

After using the virtual clinic for a 6-month period, the CIDS and ADDQoL questionnaires were reissued for completion, and patients' latest HbA1c measurements were taken if a new test had been completed during the study period. Participants' experiences were assessed at the end of the intervention using questionnaires and qualitative interviews. Five participants completed interviews and were purposively selected by usage, age, and gender to ensure the sample was representative of users. All interviews were audio-recorded and transcribed. Usage statistics were available from the system and recorded as the number of page views.

Statistical Analysis

Paired sample *t* tests were used to evaluate changes from pre- to post-test. A Wilcoxon Signed rank test was used to examine differences in the CIDS scores as they were not normally distributed. Data were considered statistically significant at *P* < .05. Descriptive statistics were used to analyze the usability questionnaires and the qualitative interviews were analyzed using content analysis.

Results

Participants

The age range of the participants who joined the virtual clinic (6 males, 11 females) was 22 to 70 years. On average, respondents had been diagnosed with diabetes for 23.5 years (SD 14.0, range 3 - 58) and had used insulin pumps for 2.8 years (SD 1.6, range 1 - 6). All were described as being of white, British ancestry. Those educated to the undergraduate level or above numbered 8 (47%). The participants all described themselves as regular Internet users. The Internet was used everyday by 11 (65%), and most used it more than once a week. On average, respondents used the Internet for 8.9 hours a week (SD 5.9, range 0.25 - 20) (Table 1).

Feasibility

Through recruitment, 19 patients were invited to take part in the intervention, and 17 joined the virtual clinic. One participant withdrew during the 6-month trial, and 4 participants failed to complete post-test questionnaires, despite using the virtual clinic for the full 6 months.

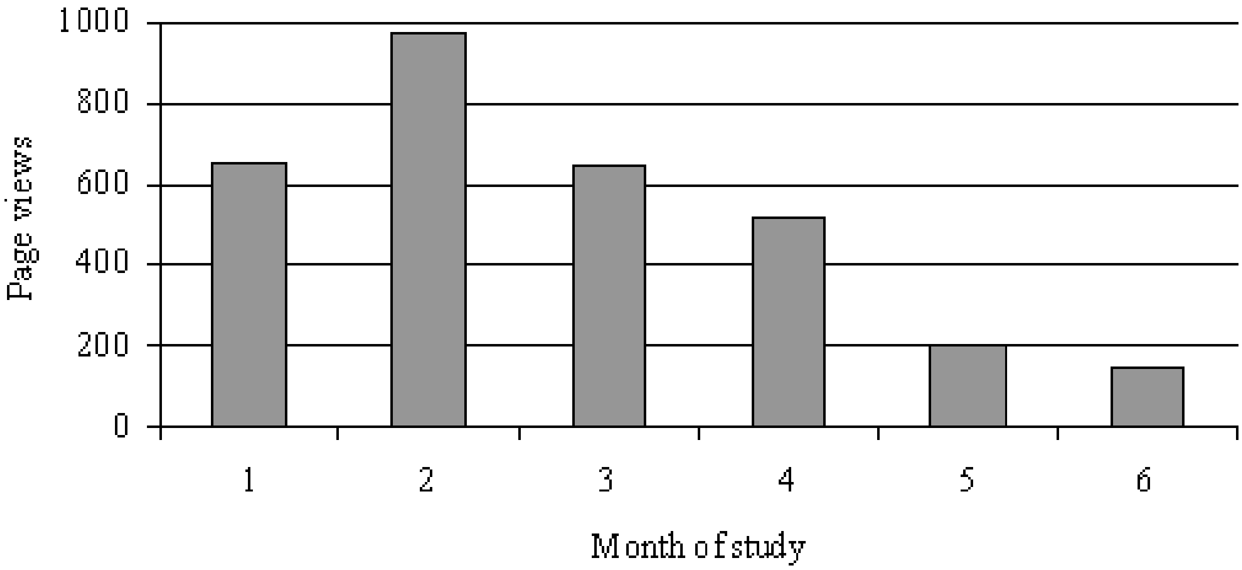
Figure 3 shows the usage of the virtual clinic and how this changed over time. In the first month, 648 page views were recorded, and this increased to 971 in the second month. Usage then gradually declined, and only 151 page views were recorded in the final month.

Acceptability

The system was rated positively by 7 users (58%) for "ease of use" with the remaining 5 (42%) rating it neutrally in the post-test questionnaires. The design of the system was rated positively by 9 users (75%), and only one user gave it a negative rating.

Despite the decline in usage, post-test interviews highlighted the fact that the intervention was very well accepted. Comments from participants included: "[T]he general contact and the facility to be able to get advice, or ask opinions of other people…without it [the virtual clinic] there isn't that facility" and "[I]t was a very positive experience". Almost all users agreed that participation in the virtual clinic had reassured them about their diabetes. Only one user expressed on the usability questionnaire that the experience of using the system was "a waste of time".

Figure 3. Number of page views per month



It was clear that users found online peer support the most valuable aspect of the intervention. The comfort they took in meeting others of like experience was expressed by two users who said, “just to have communication—to realise you are not the only person in the world like this”;“it has been so nice to realise that your problems are not unique and you’re not on your own trying to solve them”. This probably explains why the discussion board was the most used feature, with participants commenting that involvement was both “useful and reassuring”. There were 34 topics posted on the discussion board and 219 threads. Issues discussed included technical/management problems, seeking and providing emotional support, and general information seeking. No incidences of inappropriate postings were reported.

It became clear that some users posted considerably more threads than others. The most active user posted 25% of the discussion board threads. However, a post-test interview with a very low frequency user revealed that “not being so active didn’t mean that I didn’t think it was useful”, and another user commented that “if there is nothing else you need to know then that is incredibly helpful”. Participation in the discussion board was decribed as useful by 9 users (75%), and all users highly rated the virtual clinic in terms of improving communication with other people with diabetes.

Few users felt that participation in the virtual clinic had improved communication with their clinical team. Although in the follow-up interviews, participants did suggest that some features such as ordering equipment and contacting diabetes nurses were very helpful. Others commented that they did not participate in the “ask-an-expert” sessions because they were uncomfortable with using discussion forums or they simply did not have any questions to ask. In addition, the participants highlighted the fact that that contacting a clinic team for anything other than general questions would be futile, since without providing a detailed background to a problem, professionals would not be able to help.

Participants reported using the links to further information less than the other two components. Many stated they used the links initially but did not revisit them during the intervention. Despite this, only one of the participants said the links were of no use to them.

Effectiveness

Regarding HbA1c measurements, there was no significant difference found between the pre- and post-test results (*P* = .53). Because measurements were taken from patients’ files, follow up results were only available for participants who had been re-tested by their health care team during the 6-month study period (n = 8, 47%) (Table 1).

Mean ADDQoL scores (Table 1) at baseline were -2.1 (SD 1.1, range -3.4 to -0.5) compared to -2.0 (SD 1.2, range, -4.6 to -0.4) post-test (n = 12), (*P* = .62). Surprisingly, patients’ confidence in their ability to perform self-care tasks was found to be significantly reduced from baseline to follow up (*P* = .045) (Table 1). Mean CIDS scores at baseline were 89.3 (SD 6.64, range 79.8 - 98.8) compared to 83.6 (SD 14.4, range 47.6 - 98.8) post-test (n = 12). However, this finding was due to one outlier in the post-test scores of this small sample (score of 47.6, more than 2.5 standard deviations from the mean). If this outlying case were excluded from the analysis, the CIDS score would not be significantly different post-test (*P* = .08).

Table 1. Subject characteristics and test results[a]

ID #	Gender	Age	Years with diabetes	Years on pump	Internet use (hours/week)	HbA1c[b]	HbA1c[c]	CIDS[b]	CIDS[c]	ADDQoL[b]	ADDQoL[c]
1	M	70	36	3	6	7.7%		96.43		-0.11	
2	M	60	12	6	20	8.5%		84.52		-4.06	
3	M	42	3	2	5	9.6%	9.2%	94.05		-3.33	
4	F	38	25	1	15	7.0%	7.0%	94.05	89.29	-0.56	-0.72
5	F	39	16	1	0.25	7.6%		98.81		-0.53	
6	F	32	26	5	4	7.6%	7.2%	91.67	95.24	-1.83	-1.17
7	F	62	58	3	10	6.9%		88.10	84.52	-1.00	-1.75
8	M	59	30	2	14	5.7%		98.81	94.05	-3.44	-1.89
9	M	45	16	3	2	7.9%	8.6%	98.81	94.05	-3.00	-2.78
10	F	52	32	3	4	7.4%	7.2%	79.76	73.81	-2.17	-2.17
11	F	23	6	2	15	5.4%		84.52	47.62	-2.83	-4.61
12	M	47	23	6	10	8.6%	8.6%	91.67	98.81	-0.50	-0.44
13	F	30	22	1	6	8.5%		94.05	95.24	-0.89	-0.67
14	F	22	12	1	10	7.1%		72.62		-1.50	
15	F	59	16	3	14	7.0%		83.33	76.19	-2.56	-2.00
16	F	28	20	3	15	7.3%	8.2%	79.76	77.38	-3.17	-2.78
17	F	67	46	3	1	8.5%	8.8%	86.90	77.38	-3.11	-2.67

[a] Blank spaces indicate data were not available.

[b] Baseline data

[c] Post-test data

Discussion

Overview

This study has shown that use of an Internet-based system to facilitate the management of diabetes in insulin pump users is feasible and well accepted by participants. One of the goals of the pilot study was to establish that this intervention could successfully recruit and retain participants. Of the 17 participants in the virtual clinic, 16 used the system throughout the study period, representing a retention rate of 94%.

The number of people using insulin pump therapy to manage their diabetes is growing rapidly. The United Kingdom has seen a dramatic increase with the release of new guidelines in 2003 by the National Institute of Clinical Excellence (NICE) [13]. Individual success with pump therapy requires ongoing education, motivation, and psychological support [14], making insulin pump users important and ideal candidates for interventions of this nature.

The broad age range of the users in our study indicates the system has wide appeal. The fact that most users had been diagnosed with diabetes for over 12 years may have some significance. It is likely that this group of users were well practised and had developed substantial expertise in self-management. Participants were regular Internet users and most were highly educated.

There was a clear decline in use of the intervention over the 6 months. This appears to be a distinct characteristic of Internet-based health interventions and may suggest that the system became less valuable to patients over time. Our usage data follows a typical three-part process of non-usage [27]. There was an initial phase of high usage (months 1 and 2), representing the novelty of the system; a second phase of gradual decline (months 3 and 4), which may indicate that the system does not meet patient expectations or was no longer felt to be so relevant; and a third phase (months 5 and 6) where a stable user group remained. However, participants reported that non-usage was not due to dissatisfaction with the system but a reflection of the group’s experience in self-management. It appeared that a major benefit of belonging to the community was simply knowing that there was a resource available if and when it was needed. The small number of participants in the pilot study may also have had a critical effect on the viability and sustainability of this virtual clinic. It is likely that a large and consistent number of active users are required to support a system such as this, particularly to sustain discussion forums.

The discussion forum was the most used, and reported as the most useful, component of the virtual clinic system. This is in agreement with other interventions of this nature [10]. Taking part in peer discussions has shown to help patients with diabetes cope better with their illness [17] and improve adherence to management, resulting in better metabolic control [28]. Participants who answered more questions than they posted found taking part particularly encouraging. A live chat facility was also available to participants but was not used. Users mentioned that they preferred using the asynchronous discussion board as it was easier to follow and they could return to consult the posts in their own time.

Around one-third of the discussion forum posts related directly to issues regarding insulin pumps. These included books on pumping, comfortable sites for positioning the pump, and removing the pump for holidays. By having a site solely for pump users, participants were able to share information and concerns and seek advice from peers in similar situations. Future interventions may consider restricting sites to specific groups, including, for example, newly diagnosed diabetics or teenagers transitioning from pediatric to adult care, so participants can fully benefit from peer support elements.

A number of “lurkers”, people who read but seldom contributed to discussions, were identified in our intervention. Although these users did not actively participate in discussions, many still found them beneficial. Lurking has been described as a form of participation that is both acceptable and beneficial to online groups because information supplied in health-related discussion forums is often used to seek better medical care, and the same information may provide the basis for other discussions in online or offline settings [29]. Furthermore, users in this intervention felt that not contributing offered reassurance in confirming there was nothing else they needed to know.

Participants often felt that involvement in the virtual clinic had not improved their communication with their health care team. Reasons for this included having no need to contact professionals during the intervention and concerns regarding use of the Internet as a means of communication. Those who did use the links suggested they would like to receive more of their routine medical care online. These findings contrast somewhat with studies that suggest enhancing communication with health professionals is a major benefit of Internet-based health care [12]. Participants in the current study had been diagnosed with diabetes for a substantial period of time. It may be that facilities to promote communication with health teams are more useful to those newly diagnosed because their needs are different from someone who has lived with the condition for many years.

The pressure of this intervention on a clinician’s time remains to be assessed. All health care professionals involved in the study were sent questionnaires asking how they spent their time. Generally, these were not returned and highlight the need for effective measures to assess a clinician’s time expenditure. Other studies have found email communication between patients and physicians does not adversely affect a physician’s time [30].

The links to further information did not seem to be used as frequently as the other two components. This may indicate that participants were already well informed about their condition. It has been shown that people with diabetes who are highly educated and have Internet access at home are more likely to search the Web for health information [31].

Users’ responses to the virtual clinic were very positive and provide initial support for the proposal that this intervention can aid self-management. However, there was no evidence in this pilot study of improvements occurring in physiological and psychological measurements. This may be a result of the intervention’s limited timeframe or insufficient usage by participants [32]. It could also be that participants appeared to have had low information needs or that the study excluded those who might benefit more, such as those new to the disease and those new to pumping. Self-efficacy may have declined initially as patients realized that there was more about their condition to learn and understand than previously thought. It is also possible that participants’ increased attention to the topic focused their attention to the fact that diabetes is ultimately an incurable problem. Social and information support was obviously beneficial, but it was not a cure and may have increased participants awareness of all that could “go wrong”.

In addition, the current study’s results revealed high HbA1c measurements with some users disclosing difficulties in managing their diabetes, despite experience of, and adherence to, self-management regimens. Poor metabolic control has been shown to reduce a patient’s quality of life [33] and self-efficacy [34]. In addition, the CIDS scale may not have been the most appropriate instrument to use with insulin pump patients, since some questionnaire content would not apply, such as performing insulin injections.

There were several limitations to this study that would need to be addressed in any future work. There were missing data as we lost four participants to follow up and HbA1c results were only available for eight users post-test. Furthermore, there appeared to be discrepancies between the qualitative and quantitative data findings. The positive tone of the interviews was in contrast to the lack of improvements in self-efficacy and quality of life. This may have been due in part to not having follow-up data for all participants and the small sample size in this pilot study. Future work designed to draw conclusions beyond feasibility and acceptability should incorporate a larger sample. Investigating other relevant outcomes, such as social support, may also be useful in future research.

Conclusion

Overall this pilot study indicates that a virtual clinic intervention appears to be a feasible and acceptable way to provide patients with the peer support and information necessary to aid self-management. However, no improvements in biological or psychological measures could be confirmed through the data. This may be due to the complex problems this particular group of users faced in achieving good metabolic control, which may subsequently affect their quality of life and self-efficacy. The findings suggest a need for further refinement and testing of the intervention. They are being used to inform further development of Internet-based clinics and the design of larger-scale, controlled intervention studies.

Conflicts of Interest

None declared.

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Abbreviations

ADDQoL: audit of diabetes dependent quality of life
CIDS: confidence in diabetes self-care scale
CSII: continuous subcutaneous insulin infusion
INPUT: promoting insulin therapy
NICE: National Institute of Clinical Excellence

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Original Paper

Predictors of Adherence by Adolescents to a Cognitive Behavior Therapy Website in School and Community-Based Settings

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Abstract

Background: There have been no previous studies of the variables that predict adherence to online depression and anxiety intervention programs among adolescents. However, research of traditionally delivered intervention programs for a variety of health conditions in adolescence suggests that health knowledge, type and level of symptomatology, race, socioeconomic status, treatment setting, and support may predict adherence.

Objective: The aim was to compare adherence rates and identify the predictors of adherence to a cognitive behavior therapy website in two adolescent samples that were offered the program in different settings and under different conditions of support.

Methods: The first adolescent sample consisted of 1000 school students who completed the MoodGYM program in a classroom setting over five weeks as part of a randomized controlled trial. The second sample consisted of 7207 adolescents who accessed the MoodGYM program spontaneously and directly through the open access URL. All users completed a brief survey before the start of the program that measured background characteristics, depression history, symptoms of depression and anxiety, and dysfunctional thinking.

Results: Adolescents in the school-based sample completed significantly more online exercises (mean = 9.38, SD = 6.84) than adolescents in the open access community sample (mean = 3.10, SD = 3.85; $t_{1088.62} = -28.39$, $P < .001$). A multiple linear regression revealed that school-based setting ($P < .001$) and female gender ($P < .001$) were predictive of greater adherence, as were living in a rural area ($P < .001$) and lower pre-test anxiety ($P = .04$) scores for the school-based sample and higher pre-test depression scores ($P = .01$) for the community sample. A history of depression ($P = .33$) and pre-test warpy thoughts scores ($P = .35$) were not predictive of adherence in the school-based or community sample.

Conclusion: Adherence is greater in monitored settings, and the predictors of adherence differ between settings. Understanding these differences may improve program effectiveness and efficiency.

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KEYWORDS

Adolescent; prevention; anxiety disorders; mood disorders; patient non-adherence; Internet

Introduction

A number of early intervention and prevention programs have been developed to address the prevalence of anxiety and depressive disorders in children and adolescents [1,2]. However, despite the recognized importance of adherence as a factor in determining the success of a range of mental health programs [3,4], very little research has been undertaken to measure levels of adherence or to determine the factors that increase it. This paper aims to investigate factors and contexts that increase adherence to an evidence-based website offering cognitive behavior therapy (CBT) for depression and anxiety in adolescents.

Knowledge about the predictors of adherence to intervention programs in adolescent populations is largely based on research targeting physical health or smoking behaviors. Kyngäs [5], for instance, found that the adolescent's motivation, perceived threat to social well-being, and fear of the development or expression of acute problems predicted compliance to rheumatoid arthritis treatment. Studies of smoking cessation programs, on the other hand, have identified high baseline smoking rate, increased knowledge of the effects of tobacco, and white race as factors associated with improved adherence. Gender and age were not associated with outcomes [6,7]. Poor attendance for child and adolescent psychotherapy sessions and premature termination of treatment have also been found to be associated with low socioeconomic status, ethnic minority status, parental psychopathology, and severity of child psychopathology [8].

Program adherence for medical conditions among adults and children has also been found to depend on the type of treatment and program factors such as reminders, rewards, and monitoring [4]. System or program factors are also recognized as important in fostering adherence. Although not investigated in adolescents, evidence from adult studies indicates the importance of context—the setting, the amount of personal contact, and the support provided—as potentially important in maintaining adherence in both Web and non-Web environments [9]. Other predictors of adult adherence to Web-based programs have included disease severity, treatment length, chronicity, younger age, and female gender [10].

Previous research on program adherence has been hampered by imperfect data collection methods, using retrospective self-reports (which rely on good memory), and absence of social desirability bias [11,12]. Behavioral data (comprising records of use during actual exposure to a program) are a preferred method to measure adherence. Internet-based interventions programmed to record user activity are a useful platform to investigate completion rates.

The current study was designed to investigate adherence, with the level of activity on the website serving as the primary measure of this construct. A specific objective of the study was to compare the module and exercise completion rates of adolescents for a mental health website (MoodGYM) in two distinct settings. The first sample constitutes a group of users who completed MoodGYM within a classroom, where teachers provided encouragement, support, and guidance in the use of the program as part of the curriculum. Teachers did not receive specific reports on student progress through the program. The second sample consisted of community adolescent users who spontaneously logged on to the open access site. In both settings, the website program was fully automated and participant progress within the program was self-directed, with the exception that the school-based participants were directed to a different module each week. We predicted that adherence rates would be greater for the monitored classroom setting compared to the community setting. The current study also aimed to identify the demographic, setting, and symptom-related factors that contribute to adherence in the two samples.

Methods

Sample

School Sample

The school sample comprised 1000 students who completed the MoodGYM program as part of the YouthMood Project during 2006 and 2007. The YouthMood Project is a randomized controlled trial evaluating the effectiveness of the MoodGYM program among adolescents aged 13 to 17 years. Thirty schools from across Australia took part in the project. During a designated class period of 50 minutes, once a week for five weeks, students were instructed to log on to the program and individually undertake the self-directed program. Using the teacher manual, the classroom teacher provided information, support, and referral advice, if required, and maintained classroom order. No psychological intervention was provided. Approximately 60% (597/1000) of the students participating in the YouthMood Project were female, 19% (193/1000) reported living in a rural area, and 29% (287/1000) had previously been depressed.

Community Sample

The community sample consisted of 7207 adolescents from Australia who registered on the MoodGYM public site between January 2006 and November 2007. Adolescent users were identified as users who selected the age category "19 or under" when registering on the website. Approximately 72% (5223/7207) of the adolescent community users were female, with 66% (4734/7207) reporting a previous history of depression and 19% (1396/7207) indicating that they lived in a rural area.

Intervention Details

The MoodGYM program is an interactive, Internet-based CBT program designed to prevent and decrease symptoms of anxiety and depression. MoodGYM aims to modify dysfunctional thoughts and beliefs, improve self-esteem, and teach important life skills such as problem solving and relaxation. The MoodGYM program consists of five interactive modules, each of which includes information, animated demonstrations, quizzes, and "homework" exercises. A user's answers to the quizzes and exercises in the MoodGYM program are recorded in his or her own personal MoodGYM Workbook, which he or she can access any time throughout the program. Upon registering, all users consent to their data being collected and stored in a secure database for analysis. The anonymity of users is protected through the use of a pseudonym.

Measures

Users completed a number of measures prior to beginning the MoodGYM program, including the Goldberg Depression and Anxiety Scales [13] and the Warpy Thoughts Scale [14]. Demographic information was also collected, including the user's age, gender, whether they lived in an urban or rural/remote region, and whether they had a history of marked depression (yes/no).

Anxiety and depressive symptoms were measured using the Goldberg Depression and Anxiety Scales [13]. Each of these scales consists of nine items that are rated with a yes/no response. Total scale scores are calculated by summing the number of “yes” responses. Scores for each scale range from 0 to 9, with higher scores indicative of greater anxiety or depression.

The 42-item Warpy Thoughts Scale [14] was used to measure dysfunctional thinking. Users responded to the items on a 5-point Likert scale ranging from “strongly agree” to “strongly disagree.” A total scale score is calculated by obtaining the mean of the 42 items. Scores can range from 1 to 5, with higher scores reflecting more dysfunctional thinking.

Adherence Measures

The number of modules and exercises completed on the MoodGYM website were the primary outcome measures in the current study. The MoodGYM program automatically tracks and records a user’s activity on the website, including the number of log-ons and the number of modules and exercises started and completed. While the school-based users were encouraged to complete all modules of the program, the completion of exercises within the modules was optional, making this variable a good measure of adherence to, and level of engagement with, the treatment program. Since there were 28 exercises, the number of exercises completed could range from 0 to 28, while the number of modules completed could range from 0 to 5.

Analysis

Exploratory descriptive analyses and an independent samples *t* test were conducted to compare the adherence rates of the two adolescent samples. A hierarchical multiple linear regression was conducted on the combined sample to explore the predictors of adherence. In this model, the setting was entered first, followed by gender and location in the second step. Depression history was added in the third step, followed by the pre-test symptom variables of anxiety, depression, and warpy thoughts in the fourth step. In the final step, the interaction between setting and the other predictor variables was added to explore differences in adherence predictors between settings. All analyses were performed using SPSS v15 (SPSS Inc, Chicago, IL, USA).

Results

Descriptive Statistics

The mean depression pre-test score for school-based participants was 2.62 (SD = 2.42), while mean pre-test anxiety and warpy thoughts scores were 2.51 (SD = 2.44) and 2.58 (SD = .65), respectively. The mean depression pre-test score for community users was 5.46 (SD = 2.42), while mean pre-test anxiety and warpy thoughts scores were 5.50 (SD = 2.59) and 3.16 (SD = .71), respectively.

Adherence Rates

Figure 1 and Figure 2 present the module and exercise completion rates of participants in the community and school-based samples. Both module and exercise completion rates were significantly higher in the monitored school-based sample than in the community sample. In the community sample, a high proportion of adolescents completed no or only one module (6413/7206 participants, 89%) and less than five exercises (6160/7207 participants, 85%), while in the school-based sample over half of the participants completed three or more modules (483/874 participants, 55%) and nine or more exercises (526/1000 participants, 53%).

Figure 1. Number of modules completed

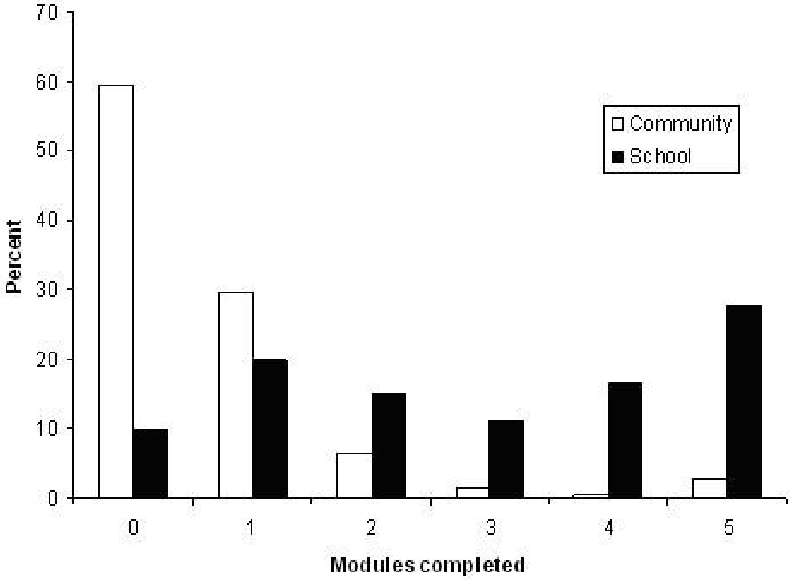
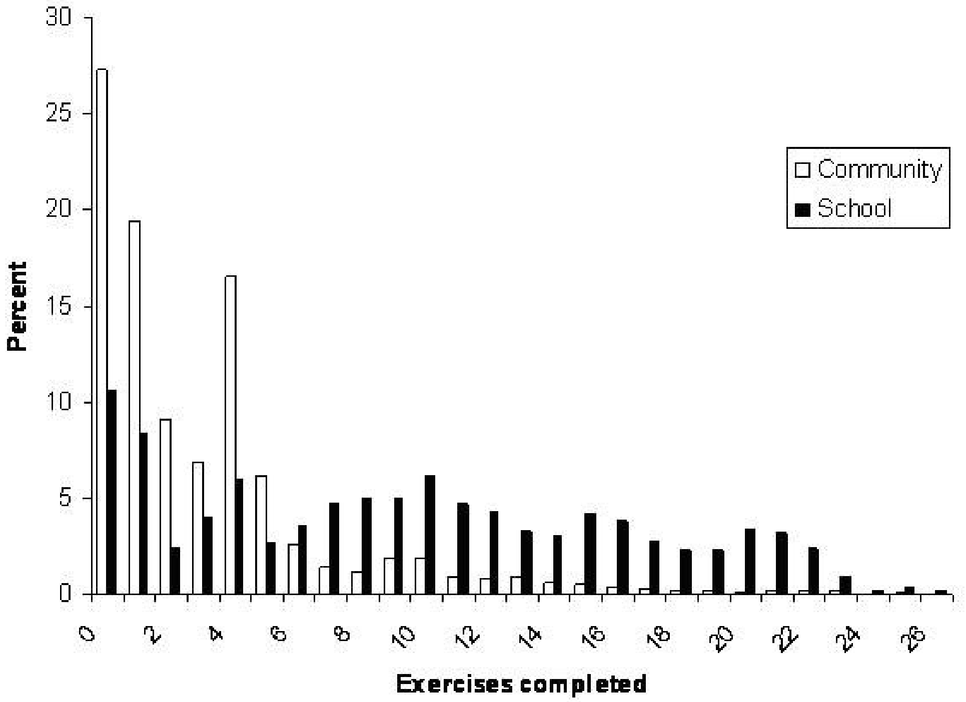


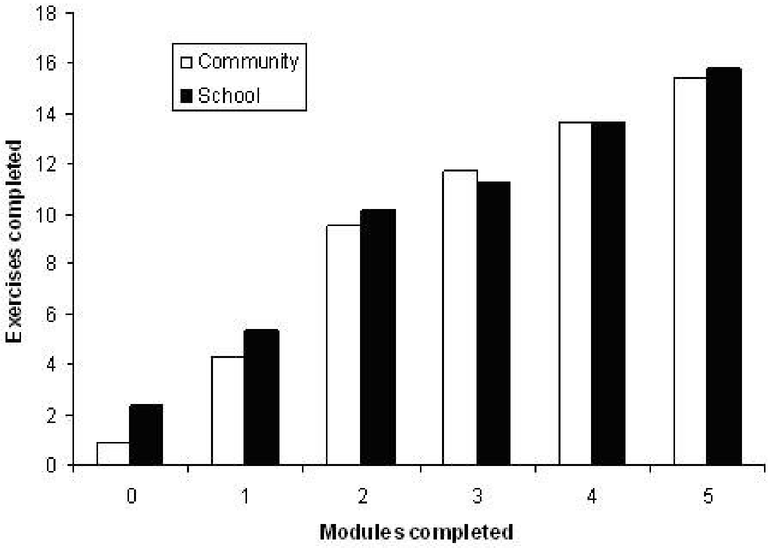
Figure 2. Number of exercises completed



Adolescents in the school-based sample completed significantly more exercises (mean = 9.38, SD = 6.84) than adolescents in the community sample (mean = 3.10, SD = 3.85; $t_{1088.62} = -28.39$, $P < .001$). Mean exercise completion rates also varied between schools in the school-based sample (mean = 10.87, SD = 4.71, range = 2.47-17.00).

Figure 3 presents the average number of exercises completed by participants as a function of the number of modules completed. This graph demonstrates that the number of exercises completed by participants in each sample is approximately equivalent once two or more modules were completed. More exercises are completed by the school-based sample when no or only one module is completed.

Figure 3. Average number of exercises completed, by number of modules completed



Predictors of Adherence

A hierarchical multiple linear regression was conducted on the combined adolescent sample to explore the predictors of adherence to the MoodGYM program and to investigate interactions of these predictors with setting. Table 1 presents the results of this analysis.

Table 1. Predictors of adherence for the combined adolescent sample

Step	Variable	Coefficient	SE	*P*
1	Setting (school vs community)	6.31	.16	< .001
2	Setting (school vs community)	6.39	.16	< .001
	Gender (female vs male)	.69	.12	< .001
	Location (rural vs urban)	.43	.14	.01
3	Setting (school vs community)	6.39	.16	< .001
	Gender (female vs male)	.69	.12	< .001
	Location (rural vs urban)	.43	.14	.01
	Depression history	−.01	.01	.67
4	Setting (school vs community)	6.55	.17	< .001
	Gender (female vs male)	.61	.12	< .001
	Location (rural vs urban)	.42	.14	.01
	Depression history	−.01	.01	.62
	Depression pre-test score	−.01	.03	.72
	Anxiety pre-test score	.07	.03	.01
	Warpy thoughts pre-test score	−.03	.09	.71
5	Setting (school vs community)	6.99	.71	< .001
	Gender (female vs male)	.65	.13	< .001
	Location (rural vs urban)	.15	.15	.31
	Depression history	−.01	.01	.56
	Depression pre-test score	.02	.03	.58
	Anxiety pre-test score	.05	.03	.10
	Warpy thoughts pre-test score	−.02	.10	.85
	Setting × Gender	−.16	.34	.63
	Setting × Location	1.82	.39	< .001
	Setting × Depression history	.34	.35	.33
	Setting × Depression pre-test score	−.23	.09	.01
	Setting × Anxiety pre-test score	.20	.09	.04
	Setting × Warpy thoughts pre-test score	−.26	.28	.35

In the final model, setting and gender were significant predictors of adherence, as were the interactions between setting and urban verus rural location, pre-test depression, and pre-test anxiety. A school-based setting and being female predicted better adherence. For the school-based sample, living in a rural area or having lower pre-test anxiety scores predicted better adherence, while higher pre-test depression scores predicted better adherence for the community sample.

Discussion

The study first aimed to compare the adherence rates of a monitored and non-monitored sample of adolescent users of the MoodGYM program. As predicted, adolescents in the school-based sample completed significantly more exercises than did community users. In terms of program completion, there was an almost 10-fold difference between the two samples, highlighting the success of the monitored setting in increasing compliance. These findings support previous research that has also found that the setting and monitoring can improve adherence by increasing motivation and interest [4,9].

An unexpected finding from the current study was that the exercise completion rates of the two samples were equivalent once two or more modules were completed. This suggests that if community users are sufficiently self-motivated to complete more than one module, they continue to engage with the MoodGYM program as strongly as participants in the monitored school-based setting.

The second aim of the current study was to identify the predictors of adherence to the MoodGYM program for the two samples of adolescent users. Participating in the intervention in a school-based setting was found to be a significant predictor of adherence, in line with previous research that has found monitored settings to yield greater adherence [4,9]. The positive relationship between female gender and adherence is also consistent with past research that has found adolescent females to be more likely to seek mental health assistance [15].

The two other predictors of adherence among the adolescent school-based sample were living in a rural area and having a lower level of anxiety at pre-test. These findings may reflect the gap in adolescent mental health services in rural areas or greater compliance and motivation among rural students and teachers. The basis for the lower rate of exercise completion among adolescents with higher anxiety scores is not clear. However, anxiety may reduce school attendance and hence reduce the opportunity to engage in the program, or it may have more direct effects on program engagement. For example, individuals may effectively avoid the program by surfing other Internet sites during the class time, they may engage in other avoidance activities, or they may fail to complete all exercises within the time specified because of rumination or worry [16]. Future research could explicitly measure these variables as a means of exploring and explaining these relationships further.

A higher pre-test depression score was identified as an additional predictor of adherence for adolescents in the community sample. Adolescents with lower pre-test depression scores may have a lower motivation to complete the program as it has less relevance or benefit to them than it does for a highly symptomatic person. Another potential reason for this finding could be that people with fewer depressive symptoms at pre-test may not require as much of the program to feel “well” and thus drop out after attaining what they need [17].

There are some limitations to the current study that should be highlighted. First, the program reviewed is Internet based and therefore the specific predictors of adherence in this study may not generalize to face-to-face interventions. The predictive ability of the setting, demographic, and symptom-related factors explored in the current study was relatively small (accounting for only 21% of the variance), suggesting that other factors may also be predictive of adherence to the MoodGYM program. Future research, therefore, should focus on measuring other potential predictors of adherence such as motivation to change, stage of change, computer savviness, perceived efficacy of computer-based programs, level of support, and personal expectations.

The variability in the exercise completion rates between schools in the school-based sample should also be investigated further. School-level predictors might include the gender distribution of students (co-educational vs single-sex), type of school (private vs public), and the socioeconomic status of the school. In addition to this, future studies should also explicitly measure the extent to which users implement the techniques taught in the MoodGYM program as a means of identifying if people actively engage with the material on the website or are simply passive browsers. This would enable a user’s engagement with the program to be more closely assessed.

We also acknowledge that there are many measured and unmeasured differences between our direct open access users and school students. It is clear that the open access adolescents had higher levels of anxiety and depression than the sample of adolescents in school classrooms. The motivation and context in which the program is likely to be undertaken is also very different. Open access users are likely to be seeking immediate help for mental health problems, while the average attendee at school may have no need for the website. These factors are likely to impact adherence rates and to confound differences between the adherence rates of the two samples described here. Nevertheless, our analyses, while identifying the importance of the difference between settings, control for this factor and provide additional information about the impact of other variables on adherence in both settings.

The clarification and identification of further predictors of adherence would enable appropriate strategies to be developed that could help improve adherence to automated Internet applications [18]. Such strategies could include tailoring the program to better address the individual needs of the adolescent (effectively reducing the amount of irrelevant material) and therapy preparation sessions aimed at a user’s stage of change or knowledge of computer-based programs. For instance, if a user is unsure of the likely effectiveness of an Internet intervention, then an education program providing details and results of the program’s success may help to increase the user’s motivation and drive to complete the program. In addition to this, automated emails to prompt log-on to the program may improve adherence. Such hypothesized strategies may enable more effective programs to be developed and implemented in the health and mental health domains.

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Conflicts of Interest

Helen Christensen and Kathleen Griffiths are authors of the MoodGYM program.

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Abbreviations

CBT: cognitive behavior therapy

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Corrigenda and Addenda

Correction: Online Advertising as a Public Health and Recruitment Tool: Comparison of Different Media Campaigns to Increase Demand for Smoking Cessation Interventions

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A number of errors regarding the cited references occurred in the article by Amanda Graham et al. (J Med Internet Res 2008;10(5):e50). The corrected version was republished on the JMIR website on 14.01.2009 at http://www.jmir.org/2008/5/e50 and resubmitted to PubMed Central; however, we have no control over other websites and aggregators which may mirror content from JMIR and may not update the original version. The corrected version can be identified by citing 60 references, while the originally published version cited only 57 references. Beginning with reference #13, citations in the text were mismatched with references at the end of the manuscript. In addition, the authors inadvertently omitted three references (#48, #58, and #59 in the corrected version).

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