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WEB-BASED INTERVENTIONS: APPLICABILITY AND MEASUREMENT FOR SELF CARE-SYMPTOM MANAGEMENT

By

DEAN J. WANTLAND

DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY
in

NURSING

in the

GRADUATE DIVISION

of the

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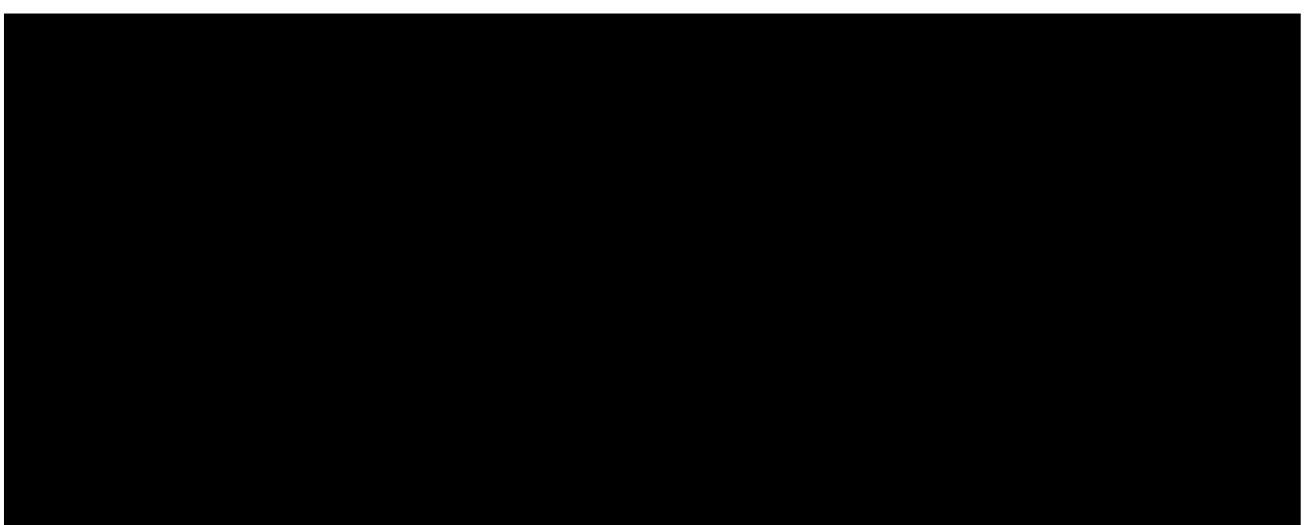

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I wish to gratefully acknowledge my advisor and mentor Dr. William L. Holzemer. Bill's constant guidance, support and vision always helps one to strive to achieve greater accomplishments than they realize they are capable of accomplishing. I have been fortunate enough to benefit from Bill's mentorship and shall carry this with me into future endeavors. I also would like to acknowledge Dr. Joseph Mullan for his patient instruction and gentle melding of his statistical knowledge to help me obtain a level of understanding that will prove useful in future studies. I also wish to acknowledge Dr. Carmen Portillo for her guidance and steady support in keeping my work on track and always making it better. I also gratefully acknowledge Dr. Eva McGhee for her direction and fundamental support. The projects with genetic mutations and resistance testing I wrote with her are a constant source of fundamental information for me, helping to frame any understanding I have about HIV/AIDS. To Franklin Hier, my friend of 25 years, who put me up and put up with me in my cross-country travels for so much of my Ph.D. studies.

I would like to acknowledge the 12,000 individuals who have participated in the studied interventions that are discussed in the text of this dissertation. The time, effort, and energy used to complete the data needs for the Investigators in their respective studies are greatly necessary and are appreciated.

Finally, to Bob, for his never ceasing support, I dedicate this dissertation.

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WEB-BASED INTERVENTIONS: APPLICABILITY AND MEASUREMENT FOR SELF-CARE SYMPTOM MANAGEMENT

By

Dean J. Wantland, MS, RN, MSN

ABSTRACT

Background: Since the early 1990's the Internet has been a conduit to provide health information and used as a forum for behavior change interventions. The rigor of the interventions in their theoretical underpinnings and the expectations of the interventions to provide sustainable longer-term outcomes has not been addressed. This is partly due to inadequate research methods and costly resources traditionally necessary to assess individuals over multiple periods.

Purpose: To ascertain the utility, efficacy, and efficiency of Internet use to provide ongoing assessments of covariates, interventions and outcomes over multiple periods. This is done by: 1). comparing the efficacy of Web based to non-Web based intervention behavior change outcomes; 2). comparing reliability of instruments in both formats; 3) monitoring the intervention dose; 4). examining Web functionality to sustain behavior change; 5). Comparing attrition rates; 6). identifying a statistical methodology to analyze change over time; 7). identifying factors contributing to behavior change success.

Methods: Three strategies were used, structured review, meta-analytical methods, and effect size analyses, to assess behavior/knowledge change interventions comparing Web based and non-Web based formats.

Pre-determined criteria were established for the selection of the studies into the analyses (paper one) and then tested (paper two) for the rigor of each study's adequacy to

the stated theoretical and/or functional framework. Third, to assess methodology for outcome change, a secondary analysis of four symptoms in 243 HIV-positive individuals taking ARVs was performed. Measurement of outcome change over time using longitudinal mixed modeling assessed the feasibility of the statistical method as a framework for ongoing longitudinal analysis of data collected in a Web-based intervention.

Findings: There is evidence that Web-based interventions improve behavioral change outcomes. Interventions directing participants to relevant, individually tailored materials reported longer Web site sessions per visit and increased visits. Sites incorporating a chat room demonstrated increased social support scores. In planning longitudinal studies, the design should include the expectation of a loss of about one quarter of the participants over time. Therefore, the analytical method selected should allow data that has uneven waves. Longitudinal mixed modeling is a feasible statistical analytical method for data collected in Web-based interventions.

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William T. Hoyt

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INTRODUCTION

The incorporation of cognitive- and behaviorally-based constructs enable health care providers and researchers to gain understanding into why individuals behave as they do and how and why individuals may be motivated to adopt varying health behaviors in the threat, presence, and treatment of illness. Controlling the onset and exacerbations of symptoms and treatment side effects is integral in many health behavior models with the goal of these intervention models being to entice individual to engage in initiating and maintaining health protective behaviors ((Fisher, Fisher, Bryan, & Misovich, 2002; H. L. Leventhal et al., 1984; University of California San Francisco Symptom Management Faculty Group, 1994).

The use of cognitive and behavior change theoretical models have been empirically tested on a number of health behaviors in many traditional interventional formats. In the last decade, the Internet has increased in popularity as a mode of interactive acquisition and sharing of knowledge and skills. The effectiveness of Web-based cognitive behavioral interventions compared to traditional, point of care and face-to-face interventions have been tested and often found, in the short term, to be more effective in achieving improvements in behaviors relative to self care management outcomes compared to non Web-based interventions. In spite of providing interactive information access and sharing methods that enhance participation in cognitive-behaviorally based interventions, behavior change in the presence of chronic illness continues to show a lack of sustainability over time (Fleury, 1992; Nguyen, Gauvin, Martineau, & Grignon, 2005).

In a number of prevention efforts, tailored interventions are reported to be more

effective that general interventions. A tailored intervention works by speaking to people based on their specific needs. In a social cognitive and stages of change construct, tailoring information is a way to help motivate people to increase their understanding of the benefits to changing behaviors. Then, as they move into action, tailoring the message is done to reduce the number of negative outcome expectations they see to changing.

A literature review to evaluate the efficacy of tailored informational interventions compared to standard informational interventions was performed by Ryan and Lauver (2002). The belief being an individual's understanding on how the health-related information relates to him/her may have stronger influences on individual behavior than does standard non-customized information on health interventions. The tailored intervention participants read, understood, recalled, and discussed the tailored material content more fully than those studies that used the standard information materials. Bender and colleagues (2003) encourage research into innovative interventions that are brief, easily implemented, and can be tailored to individual individuals, diverse clinical settings, and including urban and rural poor (Bender, Milgrom, & Apter, 2003).

Computer software and other information technology are making tailoring health messages efficient and cost-effective. In the presence of constrained financial resources to offer constant personal interaction within the clinical and social work environments to individuals to encourage and maintain behavior change, Web-based interventions incorporating online chat rooms have been shown to economically supplement personal visits (D. H. Gustafson et al., 1999). Those interventions that directed the participant to relevant, individually tailored materials reported longer Web site session times per visit and more visits. This finding is important because time in learning a task is a consistent

predictor of learning (Wellman & Marcinkiewicz, 2004).

It is the goal of this dissertation to posit a framework to support a plan for the development of an interactive web site that provides opportunities for multiple client follow up through ongoing, repeated measures research. This research is focused on the provision of targeted and tailored health information to the individual in order to encourage participation and engagement in interactive web chats with support groups and expert providers.

The second chapter (Chapter 2) is titled: "The Effectiveness of Web-Based vs. Non-Web-Based Interventions: A Meta-Analysis of Behavioral Change Outcomes". The text of this chapter is a reprint as it appears in Wantland D, Holzemer WL, Portillo CJ, Slaughter R, McGhee EM, the *Journal of Medical Internet Research*, 6 (4):e40. The co-authors listed in this publication directed and supervised the research that formed the basis for this dissertation. The article presents a meta-analytic review of current literature on the use of Web-based interventions. The purpose of the meta-analysis was to synthesize research outcomes of "web-based therapies" intended to encourage an individual's behavior change and provide a comparison with traditional intervention approaches for knowledge and/or behavioral change outcomes. Information on the dose of an intervention, rates of study participant attrition, and reliability and validity of the studies was also described.

The third chapter, (chapter 3) is titled: "The Use of Cognitive Behavioral Theoretical Models In Web-based Interventions", Wantland, Portillo, Holzemer er al, (In review). This manuscript is submitted to *Computers in Human Behavior*. This structured review was undertaken to provide further information on patient/client knowledge,

motivation, and behavioral change outcomes after Web-based interventions and sustainability of the interventions. Thirty-eight articles were selected for analysis. Twenty-four studies applied cognitive behavioral theory (CBT) as Web-based cognitive behavioral therapy interventions without further model specification. Six studies used the Transtheoretical/Stages of Change model (TTM/SOC); three studies identified self regulatory behavior change (self regulation model) as their framework; other models identified were self efficacy theory, social support theory, Orem's self care deficit theory, and Weinstein's Precaution Adoption Process Model. Rates of study participant attrition and intervention sustainability was also presented.

The fourth chapter (Chapter 4) is titled: " Using Longitudinal Mixed Modeling To Assess Concurrent, Multi-Symptom Change In Persons Living With HIV/AIDS", Wantland, Mullan, Holzemer, et al, (In committee review) will be submitted to *Nursing Research*. The goal of this analysis was to consider the magnitude of change in the slopes in individuals over time for each symptom; the effect of the symptoms upon each other; and the effects of clinical and demographic characteristics as they affect intercept and slope changes. A subset analysis from a six-month longitudinal sample of 243 HIV-positive individuals taking ARVs was studied (R01 NR04846, Holzemer, P.I.).

Finally, the fifth chapter (Chapter 5) summarizes findings from the previous articles and outlines the next phase in incorporating a Web-based intervention to assist in self-care symptom management. The intervention will focus on the identification of relevant self-care symptom management strategies that work, and will also be implemented in an environment that makes the strategies available to individuals who need them as accessible. A functional Web-based prototype and a description of the site

and the planned research was presented at the Association of Nurses in AIDS Care (ANAC). Wantland DJ, (2004), titled "The Interactive HIV Self-Care Symptom Self-Management Strategies & Symptom Management Checklist".

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ABSTRACT

Background: A primary focus of self-care interventions for chronic illness is the encouragement of an individual's behavior change necessitating knowledge sharing, education, and understanding of the condition. The use of the Internet to deliver Web-based interventions to patients is increasing rapidly. In a 7-year period (1996 to 2003), there was a 12-fold increase in MEDLINE citations for "Web-based therapies." The use and effectiveness of Web-based interventions to encourage an individual's change in behavior compared to non-Web-based interventions have not been substantially reviewed.

Objective: This meta-analysis was undertaken to provide further information on patient/client knowledge and behavioral change outcomes after Web-based interventions as compared to outcomes seen after implementation of non-Web-based interventions.

Method: The MEDLINE, CINAHL, Cochrane Library, EMBASE, ERIC, and PSYCHInfo databases were searched for relevant citations between the years 1996 and 2003. Identified articles were retrieved, reviewed, and assessed according to established criteria for quality and inclusion/exclusion in the study. Twenty-two articles were deemed appropriate for the study and selected for analysis. Effect sizes were calculated to ascertain a standardized difference between the intervention (Web-based) and control (non-Web-based) groups by applying the appropriate meta-analytic technique. Homogeneity analysis, forest plot review, and sensitivity analyses were performed to ascertain the comparability of the studies.

Results: Aggregation of participant data revealed a total of 11,633 participants (5,590 women and 5,727 men). The average age of participants was 41.5 years. In those studies

reporting attrition rates, the average drop out rate was 21% for both the intervention and control groups. For the five Web-based studies that reported usage statistics, time spent/session/person ranged from 4.5 to 45 minutes. Session logons/person/week ranged from 2.6 logons/person over 32 weeks to 1008 logons/person over 36 weeks. The intervention designs included one-time Web-participant health outcome studies compared to non-Web participant health outcomes, self-paced interventions, and longitudinal, repeated measure intervention studies. Longitudinal studies ranged from 3 weeks to 78 weeks in duration. The effect sizes for the studied outcomes ranged from -.01 to .75. Broad variability in the focus of the studied outcomes precluded the calculation of an overall effect size for the compared outcome variables in the Web-based compared to the non-Web-based interventions. Homogeneity statistic estimation also revealed widely differing study parameters ($Q_{w16} = 49.993$, $P \leq .001$). There was no significant difference between study length and effect size. Sixteen of the 17 studied effect outcomes revealed improved knowledge and/or improved behavioral outcomes for participants using the Web-based interventions. Five studies provided group information to compare the validity of Web-based vs. non-Web-based instruments using one-time cross-sectional studies. These studies revealed effect sizes ranging from -.25 to +.29. Homogeneity statistic estimation again revealed widely differing study parameters ($Q_{w4} = 18.238$, $P \leq .001$).

Conclusion: The effect size comparisons in the use of Web-based interventions compared to non-Web-based interventions showed an improvement in outcomes for individuals using Web-based interventions to achieve the specified knowledge and/or behavior change for the studied outcome variables. These outcomes included increased

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exercise time, increased knowledge of nutritional status, increased knowledge of asthma treatment, increased participation in healthcare, slower health decline, improved body shape perception, and 18-month weight loss maintenance.

KEYWORDS: Web-based intervention; non-Web-based intervention; Web-based therapy, Internet; meta-analysis; patient outcomes; adults.

NOT FOR CIRCULATION

INTRODUCTION

A primary focus of self-care and self-management interventions is the encouragement of an individual's behavior change in the presence of a chronic illness or condition necessitating knowledge sharing, education, and understanding of the condition. There has been limited research comparing the use and effectiveness of Web-based interventions to non-Web-based interventions such as traditional face-to-face interactions and paper and pencil assessments. The introduction of the Internet into clinical practice as an information-sharing medium has brought about many opportunities for innovative interventions for individuals with chronic illnesses and their care providers. These interventions are often designed to address deficiencies in patient knowledge and chronic illness self-management skills. Improvements in these areas have been shown to lead to improved health outcomes. However, the extent of the benefits gained through the implementation of Web-based self-regulatory and behavior change interventions compared to non-Web-based interventions has not been fully ascertained. This meta-analysis was undertaken to establish any potential effect size differences between Web-based and non-Web-based interventions on selected patient behavior change outcomes.

In recent years, there has been an increase in the use of the Internet to gather, transform, and disseminate information that, in earlier years, was primarily done through the use of paper, in the form of books, pamphlets, instruction materials and so on. Internet users are seeking health information and healthcare services; 80%, or about 93 million Americans have searched for at least one of 16 major health topics online (Fox & Falloes, 2003). The Robert Wood Johnson Foundation (RWJF) has noted the increased

use of Internet-based devices, cellular phones, and personal digital assistants (PDAs) creating opportunities for both patients and providers to benefit from access to e-Health applications. The RWJF has supported this trend by providing funding to study health behavior modification and chronic disease management in nontraditional settings through the use of e-Health technologies (Robert Woods Johnson Foundation, 2002). The use of computers to directly collect health assessment data from patients is a well-established technology that has been shown to produce reliable responses when administered over the World Wide Web (Bell & Kahn, 1996). In some circumstances, computer surveys have been shown to have advantages over face-to-face interviews. In one study, computer-based screening elicited more HIV-related factors in the health histories of blood donors than did standard questionnaire and interviewing methods (Locke, Kowaloff, & Hoff, 1992).Participant disclosure of high-risk sexual encounters has also been improved given the semblance of the more anonymous, Web-based data collection methodologies (Gerbert et al., 1999).

Computerized health behavior interventions are beneficial to patients/clients and healthcare providers. This is evidenced by structured reviews on the effectiveness devices such as kiosk-based computer assisted self-interviewing, interactive video, Internet applications, computer aided instruction, and the like in a variety of patient care settings. Balas and colleagues found that interactive patient instruction, education, and therapeutic programs helped individuals improve their health; at the same time, healthcare delivery processes were also improved. Research studies suggest that education and knowledge sharing benefits can be achieved through computer-based education methodologies (Balas et al., 1996; Lewis, 1999).

Interest in use of the Internet and Web-based interventions is increasing rapidly. In the 7-year period from 1996 to 2003, a total of 569 citations demonstrated a twelve-fold increase in MEDLINE publication citations for "Web-based therapies," from 13 citations in 1996 to 152 citations in 2002. There has also been a steady increase in the number of citations in MEDLINE for the term "Web-based intervention," further indicating interest in this research area for Web-based treatments. In addition to completed patient-focused, Web-based intervention studies, a large number of the publications are simply proposed or newly implemented studies. Many studies are based on therapeutic interventions that are provider focused and part of an implemented system incorporating the use of computerized medical records. Others include telehealth technologies that include highly technically interfaced lab values recorded within a case managed setting. Others discuss the variety and integrity of health-related Web sites (Figure 2.1).

METHOD

Data Sources/Systematic Review

For identification of the relevant literature, a specific search strategy was performed using explicit inclusion criteria to avoid selection bias. A MEDLINE, CINAHL, EMBASE, ERIC, and PSYCHInfo search between the years 1996 and 2003 was conducted using keyword search terms of "computerized intervention," "Internet intervention," "Web-based therapy," and "Web-based intervention." The Cochrane Library collection was also accessed using keyword searches for "Web-based intervention" and "Internet intervention." Searches in additional databases were done but revealed no new comparative Web-based published articles. A manual review of the reference lists of these articles was done to identify additional articles for possible

inclusion. When an article was identified, it was compared against established inclusion/exclusion criteria to determine its suitability for the meta-analysis. The inclusion/exclusion criteria are presented in Table 2.1.

Quality Documentation of the Studies

The quality assessment of the included studies was based on the method used by Haynes and colleagues (Haynes, Taylor, Snow, & Sackett, 1979), with modifications to address the focus of this study on Web-based interventions. The compliance to standards for the studies is based on five criteria: (1) study design; (2) selection and specification of the study sample; (3) specification of the illness/condition; (4) reproducibility of the study; and (5) outcomes specification and the measurement instruments used/validity and reliability documentation of instruments. The sum of the variables result in a total score ranging from 0 to 18 (Table 2.2). Only studies with a quality documentation score of 12 or greater were retained for the meta-analysis.

Instrument Reliability and Validity

It is important to compare Web-based study instruments to their counterpart paper-based study instruments. Structured assessment instruments can be used to reliably measure a broad range of attributes of patient health and status. For comparative purposes in a meta-analysis, it is important to know the reliability of the measurement instruments with the reliability of the item measures reported in the publication. The validity and reliability of a Web-based measurement approach itself has not yet been adequately addressed. It cannot be assumed that the validity of an instrument based on its paper format and use in a specific research situation is transferable to the instrument's use in a Web-based format. Some instruments may be modified in ways that could change their

meaning and accuracy, such that it might be inappropriate to compare data collected from different versions of the instruments (for example, provider administered assessments vs. self assessment). The ordering of the questions within an instrument can affect reliability and validity. In a Web-based format, the expected ordering may change and the ability to go back and review/change answers may need to be considered. The format of text can affect how the questions and instructions are interpreted. The use of bolding, italics, colors, fonts, and capitalization can affect the readability of items and change their phrasing. These can also draw attention to or from key parts of the instructions (White & Hauan, 2002).

Effect Size Calculation

A number of studies have been conducted having a measure that can be compared for its effect size in both a Web-based intervention vs. a non-Web-based intervention. Although the studies vary in the use of different outcomes that are used as measures for knowledge and/or behavior change, the construct of such change may be validly measured using meta-analytic techniques (Hedges & Olkin, 1985). Although most studies had multiple outcomes from which to measure knowledge and/or behavior change, using several effect size calculations to represent results from each study outcome violates the rule of independence for statistical analysis, as these outcomes were obtained from the same sample of participants and were obtained in a similar setting. Multiple outcome effect sizes will also give disproportionate weight to studies with multiple groups and multiple scales compared to studies using fewer outcome measures.

Effect size was used to quantify the effectiveness of the Web-based intervention, relative to a non-Web-based comparison intervention. Effect size analysis was done to

ascertain a standardized difference between the Web-based and non-Web-based groups, regardless of how the outcome was measured, by applying the appropriate meta-analytic technique. This analysis makes the assumption that individual studies are estimating different treatment effects and will observe the resulting effect size values and confidence intervals for distribution and variability. This check is done to evaluate if the effects found in the individual studies are similar enough that the combined effect size estimate is meaningful.

Hedges' d, a bias corrected modification of Cohen's d, was calculated to determine the magnitude of the difference between the mean of an intervention group and the mean of the control group, divided by a pooled standard deviation (Hedges & Olkin, 1985). The calculations were based on the reported data in each of the studies that provided sample sizes, means, and standard deviations for each of the Web-based and non-Web-based intervention groups for the relevant effect (outcome) variables. A homogeneity statistic, Q_w, was also calculated to determine whether the values of d used to calculate a mean effect size were consistent within the set of the reviewed studies. Heterogeneity is indicated when the Q_w statistic has a large, statistically significant value, suggesting that one or more features that were present in some studies and absent in others were affecting the magnitude of the effect sizes.

In controlled, repeated-measures studies, the effect size was calculated using the earliest time period for controls (non-Web-based intervention) and the final time period for controls then repeated for the intervention (Web-based intervention) groups, achieving one effect size for each group. The Web-based and non-Web-based group effect sizes were integrated to achieve one effect size for each study variable reviewed. In

studies where standard deviations were not reported, but *P* values and/or z scores were provided, the Stouffer method for effect size calculation was used (Rosenthal, 1991). In studies having frequency or proportion data, the Mantel-Haenszel-Peto method was used to calculate the effect size between the Web-based and non-Web-based intervention groups (Hedges & Olkin, 1985) . For those studies that had multiple methodologies (i.e., multiple Web-based intervention groups compared to one paper-based group) or for those studies that used multiple paper-based methodologies (i.e., self-completion of a paper assessment and provider interview), the multiple group means were combined, the standard deviations were pooled, and effect size calculated. In those studies using a case/control, repeated measures design, the calculations for effect size and analysis of the effect sizes were performed using D-Stat Version 1.0 (Lawrence Earlbaum Associates, Inc., Hillsdale, NJ). Graphing was done using SPSS version 11.5 (SPSS Inc., Chicago, IL). Drop-line charts for individual groups using the variables for effect size and the low and high confidence interval values were graphed to provide visual representation effect sizes and associated confidence intervals.

Descriptive statistics were used to ascertain means and standard deviations as needed for aggregating the study data. Participant attrition rates in the longitudinal studies were calculated from the group N at the time of enrollment into the study until the time of the final reported follow-up period.

RESULTS

Citation Searches

MEDLINE, CINAHL, EMBASE, PSYCHInfo, ERIC, and Cochrane Library, keyword searches resulted in 1518 citations. After reviewing for database redundancies in the citations, individual examination of the reference lists, and reviews of dissertations, a

final review against the inclusion/exclusion criteria and quality documentation resulted in 20 studies selected for the instrument format analysis and the intervention-focused meta-analysis for behavior change outcomes. The selected studies were performed in the United States, France, Japan, Italy, Spain, Netherlands, Sweden, and Germany.

Exemplar studies, not selected for analysis, are summarized as follows: Studies that were Web-based to Web-based intervention comparisons (Barrera, Glasgow, McKay, Boles, & Feil, 2002; R. Glasgow, Boles, McKay, Feil, & Barrera, 2003; McKay, King, Eakin, Seeley, & Glasgow, 2001; Tate, Wing, & Winett, 2001); 2) Studies that were descriptive of the functionality of a Web site (Alcaniz et al., 2003; Gomez, Caceres, Lopez, & Del Pozo, 2002); 3) Studies that were provider focused (Meigs et al., 2003); 4) Pre/post intervention studies that only assessed the Web-based intervention (Atherton, 2000; Bensen et al., 1999; Etter, Le Houezec, & Landfeldt, 2003; Lenert et al., 2003; Nebel et al., 2002; Takabayashi et al., 1999); 5) Studies that did not provide adequate information regarding either a change in outcomes or the comparative utility/validity/reliability of the Web-based tool (Flatley-Brennan et al., 2001; D.H. Gustafson et al., 2001; Ojima, Hanioka, Kuboniwa, Nagata, & Shizukuishi, 2003); and 6) Computer-assisted instruction (CAI) studies (Anderson, Winett, Wojcik, Winett, & Bowden, 2001; Clark et al., 1997; Jennt & Fai, 2001).

Characteristics of the Reviewed Studies

Review of the selected articles revealed variation in design of the Web-based intervention studies. Because of the variation in the framework for these studies, two separate analyses were performed that: (1) evaluated studies that focused on a one-time, cross-sectional survey comparison of assessment instruments/methods when administered

to Web-based and non-Web-based groups (Bangsberg, Bronstone, & Hofmann, 2002; Bell & Kahn, 1996; Fang Yu Chou, 2003; Soetikno, Mrad, Pao, & Lenert, 1997; Wu, 2000); and (2) evaluated outcomes variables of intervention that best indicated knowledge and/or behavior change resulting from a Web-based intervention. A summary of each study is shown in Table 2.3.

Aggregation of data from the 22 selected studies showed a total of 11633 participants in both the Web-based and non-Web-based interventions at the time of inclusion into their respective studies. Of this total, 5,590 were women and 5,727 were men. The average age of participants was 41.5 years. For longitudinal studies, the average intervention duration was 27 weeks with a range from 3 weeks to 78 weeks. Attrition rates for the longitudinal studies revealed that both the intervention and control groups lost an average of 21% of the study participants over the duration of the studied interventions. (Table 2.4).

Knowledge and Behavioral Change Outcomes

Sixteen of the 17 studied effect outcomes revealed improved knowledge and/or improved behavioral outcomes for participants using the Web-based interventions. The individual effect sizes for each of the reviewed study variables for knowledge change and/or behavioral change showed effect sizes ranging from small (±.01 to .19); to moderate (±.20 to .47); to moderately large (.54 to .75). Of the 17 studied outcome variables, six showed that the positive effect sizes were statistically significant as seen by the confidence intervals being greater than zero (Figure 2.2). The one study favoring non-Web-based interventions did not show statistical significance. There was no significant difference between the length of an intervention and effect size for the studied outcome.

Review of the forest plot graphical output figures showed a high degree of heterogeneity indicated by the confidence interval overlap (Figure 2.2). Estimation of the homogeneity statistic was calculated and was statistically significant indicating variation between the 17 studies ($Q_{w16} = 49.993$, $P \leq .001$). Sensitivity analysis to ascertain the studies with the greatest heterogeneity, revealed three standout studies.

Assessment Instrument/Methods Comparison

The five studies comparing assessment instruments/methods when administered to Web-based and non-Web-based groups revealed two studies showing moderate negative effect sizes (Wu -.24; and Soetikno -.22) favoring the paper-based/traditional format. The remaining three instrument/method comparison studies showed small to moderate positive effect sizes ranging from .17 to .44. One of the five studies, showed a statistically significant effect size, indicated by zero being included in the confidence interval, the remaining four studies showed no statistically significant effect size comparison indicating little variability between the format of the instrument/method being either Web- or non-Web-based (Figure 2.3). Analysis of homogeneity of these five studies revealed a statistically significant Q value ($Q_{w4} = 18.238$, $P \leq .001$).

DISCUSSION

Advantages for the Use of Web-based Interventions

The management of any chronic disease should be personalized to an individual, as the person is ultimately responsible for the success of the intervention. Self-management of a chronic condition and contribution to disease management has demonstrated improved results and adherence to treatment regimens. Consequently, Web-based interventions should be designed to allow individuals to tailor the intervention to their specific needs. With the advent of high-level Web programming

languages, intended to provide effective data and information provision and retrieval, the flexibility to provide interactive and responsive programs for use on the Internet is increasing. This is conducive to the incorporation of interactive and continuous self-monitoring, feedback and information exchange that is certain to play an increasingly important role for this patient care need.

Comparative Intervention Studies

Although the studies vary across many clinical areas of interest, there is a consistency of the selected outcome variables being targeted to require either or both an individual's knowledge and behavior change to achieve the outcome. The review of the individual study effect size comparisons in the use of Web-based compared to non-Web-based interventions showed an improvement in individuals using Web-based interventions to achieve behavior change for the studied outcome effect variables. The broad variability in the focus of the studied outcomes precluded the calculation of an overall effect size for the compared outcome variables in the Web-based when compared to the non-Web-based interventions. Additionally, a homogeneity statistic estimation also revealed widely differing study parameters ($Q_{w16} = 49.993$, $P \leq .001$). Therwawsweoinrwr ascertained three studies with the greatest heterogeneity, these studies were not excluded from the analysis as their contribution to the research using Web-based and non-Web-based interventions showed significant findings. There was no significant difference between study length and effect size in the longitudinal studies.

Assessment Instrument/Method Comparison Studies

A comparison of the five Web-based instruments and the non-Web-based instruments shows the variability between the formats of the instrument to be moderate to

small. The effect size analysis confirms the respective authors' findings in each of their studies. For the studied instruments, the Web-based instruments produced valid and reliable results. These studies revealed effect sizes to range from -.25 to +.29, only one of which was statistically significant, favoring Web-based interventions. In the studies that measured the use of quality of life (QOL) instruments such as the MOS-HIV and the SF-36, it should be noted that in the Bell and Kahn study, there was no specification of any predisposing illness in the Web-based intervention group. In the non-Web-based population, the scores reported by the authors of the comparative study, were combined from studies with participants having varying illnesses, which may account for this comparison group having worse SF-36 scores than the anonymous comparison group. Further, these QOL instruments may not be sensitive enough to capture the illness severity of the subscales for Web-based clients. Floor effects have been reported for the SF-36 for those with severe illness related impairment. Conversely, ceiling effects may be present if the Web-user is doing well and not experiencing levels of debilitation due to symptoms. The MOS-HIV and SF-36 may not possess sufficient sensitivity to change to adequately reflect the symptom experience and management of symptoms in ongoing tailored interventions requiring daily or weekly input.

Demographic Characteristics

Most of the studies explained the possibility of demographic differences (i.e., culture, age, gender, ethnicity, and/or income) in their study intervention populations. Some studies controlled for the possibility of these differences, while others provided training to the Web-based intervention participants. In the reviewed studies, the average age of the study participants was 41.2 years, which is relatively young. It is likely that

this is not the same population who are living with many chronic illnesses. Most of the studies did not discuss issues such as ethnicity, income level, or homelessness, which are important when considering the use of a Web-based technology to deliver an outpatient intervention. All but one of the studies did report gender, but overall, the differences between participation of men and women were not large in the studies. Two studies looked at HIV interventions and had a preponderance of men (N = 237) with an average age of 37.5 years. The studies by Bell, et al. and Christensen, et al. were open access Web sites and had lower average ages compared to their non-Web-based control groups.

Dose of an Intervention

There are tools available that ascertain use of a Web site, visits to a various pages on the site, and paths to trace links and usage patterns by the user. These are useful to determine the dose of the Web-based intervention. Based on the individual's response, how much intervention that is needed by an individual can be tailored and varied. In the reviewed studies that discussed their Web site use statistics, (see Table 5) there was large variability in the average intervention time and the number of logons to the sites. The average session site time of 17.3 minutes should be considered in context of the attributes of the individual using the Web site and the burden the intervention may place on the individual to complete the items and contribute any necessary interactive responses. The burden to complete the needed information throughout the site may be relieved by increased interactivity to create and maintain interest in the site. Interactivity may help reduce attrition of Web users and provide benefits in producing positive behavioral change.

Variation in Study Validity

The comparative intervention studies invited participation into their studies either by e-mail or by in-person enrollment. In all these studies, personal information for continued contact (i.e., telephone number, mailing and e-mail addresses) was obtained. This is in contrast to some studies in the instrument comparison study group where self-identification and e-mail participation was obtained for the Web-based participation and the participants were anonymous.

Selection bias may be introduced, as it is possible that Web-savvy clients and researchers may have differing attributes from non-Web-familiar clients and researchers. Familiarity with the use of computers and the Internet may lead to self selection in the use of these technologies. Conversely, non-familiarity with computers and the Internet may lead others to refrain from participation, increasing attrition in these interventions. In addition, some of the anonymous Web-based participants who may have completed the assessments may not have truly met the criteria for the study. Additionally, publication bias is possible as there is the possibility of missed publications in spite of the systematic literature review process.

CONCLUSION

There is substantial evidence that use of Web-based interventions improve behavioral change outcomes. These outcomes included increased exercise time, increased knowledge of nutritional status, increased knowledge of asthma treatment, increased participation in healthcare, slower health decline, improved body shape perception, and 18-month weight loss maintenance. Those interventions that directed the participant to relevant, individually tailored materials reported longer Web site session times per visit and more visits. Additionally, those sites that incorporated the use of a chat room demonstrated increased social support scores. The long-term effects on individual persistence with chosen therapies and cost-effectiveness of the use of Web-based therapies and hardware and software development require continued evaluation.

ABSTRACT

The incorporation of cognitive- and behaviorally-based constructs enable health care providers and researchers to gain understanding into why individuals behave as they do and how and why individuals may be motivated to adopt varying health behaviors in the presence of illness or threat of illness. A structured review of recent Web-based intervention studies using cognitive behavioral theoretical models from psychological, nursing, and related disciplines is presented. This review was undertaken to provide further information on individual knowledge, motivation, and behavioral change outcomes after Web-based interventions and sustainability of the interventions. Thirty eight articles were selected for analysis. Twenty four studies did not specify a cognitive behavioral theory or model. Six studies used the Transtheoretical/Stages of Change model (TTM/SOC); Three studies identified self regulatory behavior change as their framework. Two studies each identified Self Efficacy Theory and Social Support Theory. The median attrition rate was 26% over the duration of the studied interventions. Fifty five percent of the studies lasted three months or less, and 47% lasted two months or less. The design and analytical methods for future studies should include theoretical constructs that explicitly and repeatedly measure motivation and motivation change relative to the behavior change over a longer period.

KEYWORDS
Cognitive behavioral theory, Transtheoretical model; self regulation model; Web-based intervention

INTRODUCTION

Cognitive and behavior change theories and models have been guiding primary and secondary prevention interventions for a number of populations. Often, these theories and models identify what should be monitored, measured, compared or evaluated in intervention research, guiding the application and generalization of research findings into patient care practice. The incorporation of cognitive- and behaviorally-based constructs enable health care providers and researchers to gain understanding as to why individuals behave as they do and how and why individuals may be motivated to adopt varying health behaviors in the presence of illness or threat of illness.

(Glanz, Lewis, & Rimer, 2002) explain that a cognitive/behavioral model is a way of applying the overarching theory by making the assumptions behind program strategies and methods explicit. Theories have constructs and concepts that models operationalize by using variables that represent the constructs in measurable forms. The variables can be traced back to a theory, but they are application specific, with designated meaning and associations used to specify their relationships in the model .

The use of cognitive and behavior change models have been empirically tested on a number of health behaviors in many traditional interventional formats. In the last decade, the Internet has increased in popularity as a mode of interactive acquisition and sharing of knowledge and skills. The effectiveness of Web-based cognitive behavioral interventions compared to traditional, point of care and face-to-face interventions have been tested and often found to be more effective in achieving improvements in behaviors relative to self care management outcomes compared to non Web-based interventions (Wantland, Holzemer, Portillo, McGhee, & Slaughter, 2004) (Kirsch & Lewis, 2004). In

chronic illness interventions and maintenance studies, cognitive and behavioral models for both traditional and Web-based interventions to encourage behavior change continue to show a lack of theoretical clarity and sustainability for the desired behavior change outcomes over time (Doshi, Patrick, Sallis, & Calfas, 2003; Fleury, 1992; Nguyen et al., 2005; Sallis, 2001).

METHODS

A review of Web-based intervention studies from psychological, nursing, and related disciplines is presented as a survey of commonly used cognitive behavioral models. Guided by the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) model (R. E. Glasgow, Goldstein, Ockene, & Pronk, 2004; Orleans, 2005) for the evaluation of health behavior change research, a multi-item structured review framework depicting how well the research variables studied support the constructs of the theoretical model is provided. This structured review was done for all identified theoretical models used in two or more studies. The identified theoretical models used in one study only were not evaluated and is presented as NA in the theoretical criteria evaluation. Based on the identified models, a summary of the theory and how well the results support the use of the model, and any evidence of sustainability of the outcomes utilizing the designated intervention are also provided.

Data Sources/Systematic Review

For identification of the relevant literature, a specific search strategy was performed using explicit inclusion criteria to avoid selection bias. A MEDLINE, CINAHL, EMBASE, ERIC, and PSYCHInfo search between the years 1996 and 2004 was conducted using keyword search terms of "computerized intervention," "Internet intervention," "Web-based therapy," and "Web-based intervention." The Cochrane

Library collection was also accessed using keyword searches for "Web-based intervention" and "Internet intervention." The number of studies identified was 2,034. Searches in additional databases were done but revealed no new comparative Web-based published articles. A manual review of the reference lists of these articles was done to identify additional articles for possible inclusion. When an article was identified, it was compared to the established inclusion/exclusion criteria. The inclusion and exclusion criteria for this review are presented in Table 2.1. If an article was found to be a pilot study for a subsequent intervention with published results, only the latter was included in the analysis.

RESULTS

Thirty-eight articles delineating a cognitive behaviorally based theory are included in this structured review. Six studies used the Transtheoretical/Stages of Change model (TTM/SOC) as the theoretical framework (Bock, Marcus, Pinto, & Forsyth, 2001; Escoffery, McCormick, & Bateman, 2004; Gullette & Turner, 2004; Marshall, Leslie, Bauman, Marcus, & Owen, 2003; Miller et al., 2002; Wang & Etter, 2004). Three studies identified self regulatory behavior change (self regulation model) as their framework: (Clark et al., 1997; Nebel et al., 2002; Takabayashi et al., 1999). Twenty four studies applied cognitive behavioral theory as Web-based cognitive behavioral therapy interventions without further model Specification:(Anderson et al., 2001; Andersson, Stromgren, Strom, & Lyttkens, 2002; Bruning Brown, Winzelberg, Abascal, & Taylor, 2004; Buhrman, Faltenhag, Strom, & Andersson, 2004; Carlbring, Ekselius, & Andersson, 2003; Celio et al., 2000; Chesney, 1997; Christensen, Griffiths, & Jorm, 2004; Clarke et al., 2002; D.H. Gustafson et al., 2001; D. H. Gustafson et al.,

1999; Harvey-Berino et al., 2002; Homer et al., 2000; Krishna et al., 2003; Lange et al., 2003; Lenert et al., 2003; Long & Stevens, 2004; Ritterband et al., 2003; Southard, Southard, & Nuckolls, 2003; Strom, Pettersson, & Andersson, 2000; Winzelberg et al., 2003; Winzelberg et al., 2000; Zabinski, Wilfley, Calfas, Winzelberg, & Taylor, 2004). Additionally, five studies, identified other cognitive behavioral models as the study framework, these models were self efficacy theory (R. Glasgow et al., 2003; Lorig et al., 2002), social support theory (Barrera et al., 2002), Orem's self care deficit theory (F. Y. Chou, Holzemer, Portillo, & Slaughter, 2004), and Weinstein's Precaution Adoption Process Model(Oenema, Brug, & Lechner, 2001).

Overview of all studies

Of the 38 reviewed studies, the number of enrollees in each study ranged from 22 participants to 18,361 participants at the reported start of each study. Review of the designs of each study showed four (11%) had a cross sectional design, four (11%) were designed using a pre-post methodology with a duration from one week pre/post to 26 weeks pre/post intervention. Thirty (78%) had a longitudinal intervention/control design. The duration of the longitudinal repeated measures studies ranged from three weeks to three years. Of the longitudinal studies, twenty-one (55%) of the studies lasted 3 months or less, and eighteen (47%) lasted two months or less. Six studies (16%) reported on interventions lasting one year or longer.

Seventeen of the 34 pre/post and longitudinal studies reported the loss of participants. Attrition rates percentages for the repeated measures longitudinal and pre-post design studies, revealed that both the combined intervention and control groups lost an average of 28.2% (range 2.5% to 80%). The median attrition rate was 26% over the duration of the studied interventions.

Effect size analysis for the longitudinal intervention/maintenance studies lasting one year or longer could be estimated for five of the six studies. Two of the six studies (Bock et al., 2001; Harvey-Berino et al., 2002), showed a significant effect size for an increase in physical activity levels pre and post intervention (d=.34, 95%, CI=0.02 to 0.70, $p \leq .05$ and d=.63, 95% CI=0.20 to1.09, $p \leq .05$) respectively compared to the non-Web based control groups. One intervention, (Krishna et al., 2003), showed a significant effect size for an increase in users knowledge of asthma (d=.0.40, 95%, CI=0.14 to 0.66, $p \leq .05$) compared to the non-Web-based control group. Two studies (Lorig et al., 2002) and (Andersson et al., 2002), did not show statistically significant effect size for the studied behavioral (self efficacy) change outcomes of back pain self management, (d=.03, 95%, CI=-0.11 to 0.16 and tinnitus self management behavior change (d=.16, 95%, CI=-0.21 to 0.25 respectively compared to the control interventions. One study (Wang & Etter, 2004) did not provide adequate behavior change detail to estimate effect sizes.

Cognitive Behavioral Therapy and Web-Based Interventions

A number of the identified web-based interventions described the use of Cognitive Behavioral Therapy (CBT) as the framework for the intervention design. These studies do not describe any theoretical framework or model and are often mental health interventions. These intervention studies often are multi faceted, providing varying levels of interaction to the user. These interventions are similarly structured to person-to-person sessions and utilize comparable tools that are used in person-to-person sessions. In the early phase of treatment, the web based intervention serves as a method in providing instruments to measure an individual's perception and belief system relative to the focus of the intervention. At the next level, the web-based intervention materials

provide behavioral strategies that are tailored to the individuals needs based upon their responses from the obtained information. These tailored materials include problem solving techniques, resolutions for negative perception, and action to promote responsibility. Additionally, the web-based intervention serves as a tool for the individual to document their thoughts and feelings in an online diary that, depending on the intervention, is read by the practitioner(s) and feedback is provided. Implicit in the interventions that incorporate CBT is that self perception, faulty cognitive thought, and/or maladaptive behavior and emotional response can be identified and addressed resulting in improved self efficacy. Figure 3.1. presents a simple model showing how antecedents, behavior, and cognitions interact.

Findings for the Studies Using CB-Theoretically Based Interventions

As a measure for assessing how well each study incorporating CBT followed the premise of the theoretical model, a set of four criteria were used. The study: 1) provided tools to identify the cognitive problem; 2) provided educational materials; 3) provided application methods for use by the user; and 4) provided measures to assess self efficacy change or self management change at multiple time periods (if it was a longitudinal study). Nearly all of the studies met the four criteria indicating completeness of the transition of the paper-based instruments to a web-based format. Table 3.2. summarizes these results.

Although studying the value of Web-based interventions as a modality to provide therapy to individuals is important, the interventions identified to have used a general cognitive behavioral model did not explicitly address the self regulatory, self efficacy, or individual motivational influences that are intrinsic in cognitive behavioral theoretical constructs. Instead, these interventions studied *how* the employed Web-based model of intervention succeeded or not in changing a behavioral outcome rather than studying the construct of change in self efficacy,

self regulation, or individual motivation that influences a change in a behavioral outcome over time.

Research findings from the remaining fourteen of reviewed studies showed that many researchers did address the use of specific cognitive behaviorally based theoretical models to guide their Web-based interventions. Nine of the studies used either the Transtheoretical/Stages of Change model or the Self-regulation model. These models are each presented separately and the representative studies were reviewed for their theoretical design, study design, methods for analysis, and outcomes. Statistically significant positive outcomes or positive effect sizes were noted in nearly all the studies, necessitating a secondary step for ascertaining whether the types of study questions, study instruments, and results were consistent with the identified theoretical framework.

The Trans-Theoretical Model of Behavior Change (Stages Of Change Model)

Individuals who are learning to live with chronic illness are not always ready or willing to alter their habits and routines that may be necessary to improve the quality of the individuals life. Levels of motivation vary substantially even among those who appear to be urgently in need of help. Some individuals are highly motivated to address their health problems but others are not remotely interested in change, and may in fact be resistant to it. A framework to assess individual motivation was developed by two American psychologists, Joseph Prochaska and Richard DiClemente. The Transtheoretical Model of Behavior Change (TTM) is so named because it incorporates elements from a number of other psychotherapy and behavior change theories into its structure. The model emerged from a comparative analysis of leading theories of psychotherapy and behavior change and uses stages of change to integrate processes and principles of change. The major premise of the model is that people progress through a

series of stages when they attempt to change behavior. Five stages have been proposed and are depicted in Figure 3.2. The first stage, Precontemplation, includes people who have no intention of taking action in the foreseeable future (Prochaska, DiClemente, & Norcross, 1992), define foreseeable future as within the next six months. More recent revisions of this stage have lead to three sub-classifications noted as: unaware - individual has no idea that there is problem behavior; uninvolved - individual knows that the behavior needs to be changed but does not perceive the problem as urgent; and undecided - considering the positive and negative consequences of the change (Elder, Ayala, & Harris, 1999). Contemplation is the second stage, in which people intend to change within the next six months. Individuals are becoming aware of the pros of changing, but remain acutely aware of the cons of change. The next stage, preparation, includes people who intend to take action in the immediate future (usually within the next month). Often, some significant action has been taken in the last year and these people have a well-defined plan for undertaking the behavior change. Action is the stage in which people have made specific modifications in their lifestyles within the past six months. Usually, subjects in this stage are required to meet and sustain some observable behavior (i.e., abstinence from smoking) for at least six months. After time has elapsed, the behavior is considered ingrained into the individual's life and they may enter the maintenance stage where individuals work to prevent relapse, and continue the behavior.

Findings for the Studies Using the TTM/SOC Model

As a measure for assessing how well each study incorporating the TTM followed the premise of the theoretical model, a set of three criteria were used: 1) documentation of the initial stage of the study participants; 2) documentation of outcomes by

motivational stage; and 3) documentation of change in the study outcome by individual or group of individuals over time. Of the six studies using the TTM/SOC model, three did not provide any information on changes in the participant's studied outcomes over time and one study does not document the initial stage of the participants in the intervention utilizing the SOC model. The remaining three studies did document evidence for the theoretical criteria. Table 3.3. summarizes the studies incorporating the TTM/SOC as the theoretical framework.

The Self-Regulation Model

Self-regulation is an especially relevant construct from social learning (Social cognitive) theory for developing self-care management interventions to control an illness. Being self-regulating means being observant and making judgements based on observation (vs. habit, fear, tradition, etc.). It entails reacting appropriately to one's own efforts to bring about change. The model is also predicated on the idea that self-regulation processes are continuous and reciprocal. The ability of a person to be self-regulating is central to achieving desired health outcomes. The power of the outcome is associated with how closely held a value it represents for the individual (Bandura, 1991).

The Self-Regulation model is intrinsically a two-level model; synthesizing both the concrete experience of illness with an abstract perception of the illness. Originally constructed in the mid 1970's by Howard Leventhal and Jean Johnson (1976), the model theorizes that individuals create mental representations of their illness based upon their present knowledge base of the illness and shape their perception of the illness based upon available knowledge and information and synthesis of new information available to them (H. Leventhal, Diefenbach, & Leventhal, 1992). Information received from health care

professionals and other authoritive information sources is incorporated into the individual's frame of knowledge, further molding or reshaping his or her illness representation. Based upon these sources of reference, an individual applies their symptom experience to again reshape their frame of reference to their perception of their illness and enhancing self-management abilities. It is hypothesized that it is in this reappraisal and coping phase where interventions are beneficial.

As can be seen from Figure 3.3, the Self regulation model is comprised of four dimensions of 1) cause, 2) consequences, 3) identity, and 4) timeline (Meyer, Leventhal, & Gutmann, 1985). Further measures to identify the controllability (self efficacy) dimension (Lau & Hartman, 1983) is also noted in the model.

Findings for the Studies Using the Self Regulation Model

The criteria to assess how well each of the three studies incorporated the dimensions of the Self Regulation model is the presence or not, of each of the dimensions being measured. The summarized results in Table 3.3, show that all three studies identified the individuals perceptions of illness cause, illness consequences and illness controllability. Only one of the three studies documented the illness identity and illness timeline (being acute or chronic) dimension.

Self Efficacy and Social Support Theoretical Model Applications

Self-efficacy determines the amount of expended effort and persistence when there are obstacles or aversive experiences (Bandura, 1982). In self-efficacy theory, observed models of behavior and subsequent behavior change are dependent on internalized, cognitive processes that are necessary for behavior change to take place. The motivation to change derives primarily from (1) outcome expectations, that is, the

perception that undertaking an action will enable people to achieve their goals, and (2) efficacy expectancies (self-efficacy) – the perception that one is capable of the action.

Two studies specified using Self Efficacy Theory as the framework for components of their behavior change research. One study, (R. Glasgow et al., 2003) also incorporated Social Support theoretical constructs into the research on the effects of internet support dialogue to enhance utilization, motivation and outcomes. Social Support theory was also specified in one additional study. The criteria to assess how well each of these four studies incorporated the dimensions of Self Efficacy Theory and/or Social Support Theory is the presence or not, of each of the dimensions being measured. These results are also summarized in Table 3.3.

DISCUSSION

Many of the intervention studies invited participation into their studies either by e-mail or by in-person enrollment. In all these studies, personal information for continued contact (i.e., telephone number, mailing and e-mail addresses) was obtained. This is in contrast to some studies where self-identification and e-mail participation was obtained for the Web-based participation and the participants were anonymous. Selection bias may be introduced, as it is possible that Web-savvy clients and researchers may have differing attributes from non-Web-familiar clients and researchers. Familiarity with the use of computers and the Internet may lead to self selection in the use of these technologies. Conversely, non-familiarity with computers and the Internet may lead others to refrain from participation, increasing attrition in these interventions. However, in prior studies, no differences in the attrition rates of Web-based or traditional interventions was noted (Wantland et al., 2004). This analysis provides evidence that the

design of such studies should include the expectation of a loss of about one-fourth of the participants over time.

It is possible that some of the anonymous Web-based participants who may have completed the assessments may not have truly met the criteria for the study. There is also the possibility of publication bias where only interventions showing significant findings are published. Additionally, there is the possibility of missed publications in spite of the systematic literature review process.

An important predictor of behavior and changing behavior is an individual's behavioral intention (Montano, Kasprzyk, & Taplin, 1997). However, only five studies out of the 38 reviewed in this analysis focused on individual motivation and his/her intent to change behavior over time. Behavioral intention is the perceived likelihood of performing the behavior and is determined through one's attitude toward performing the behavior and subjective norm. An individual with strong positive beliefs regarding an outcome will have a positive attitude toward acknowledging that behavior. Similarly, a person who believes that others think a behavior should be performed, and who is motivated to comply with those expectations, will have a positive subjective norm. Alternatively, an individual with mostly negative beliefs of the outcome of a behavior will have a negative attitude toward that behavior. Accepting these intentions, the design and analytical methods for future studies should include theoretical constructs using models that explicitly target measures of an individual's behavioral intention and interest in an intervention at the outset of an intervention study with repeated measurements over the course of the intervention.

CONCLUSION

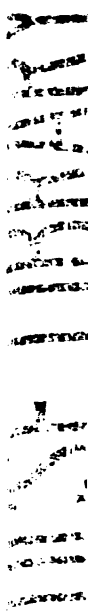
Changes in behavior, have been empirically tested in many studies, providing evidence claims to support positive outcomes for theoretically based programs in varying chronic illnesses. The behavior change occurs through enhancing an individuals belief in his /her own ability to change their behavior to achieve a goal. These abilities lead to the growth of a participants' self-confidence to manage illness- and treatment-related symptoms.

Benefits to be gained from the use of Web-based interventions can be anticipated as nearly all the identified studies noted significant statistical and/or effect size results for one or more of their studied outcome change variables. The identified models reveal evidence that interventions and behavior change maintenance both explicitly or implicitly guided by cognitive behavioral theoretical models in Web-based interventions improve an individual's behavioral change. Such outcomes include smoking cessation, back pain reduction, reductions in recurrent headaches, increased exercise time, increased knowledge of nutritional status, 18-month weight loss maintenance, increased knowledge of asthma treatment, increased participation in healthcare, improved body shape perception, and positive depression score changes.

The use of the Internet to provide Web-based interventions has been proven to be a valid and reliable modality for presenting information and support to users. Although Web-based interventions have the potential for maintaining participation of individuals at a low marginal cost, maintaining the participant's interest in the ongoing use of the intervention over an extended period of time is needed. The length of the interventions reviewed in this analysis were generally three months or less, which does not provide adequate information for sustainability of the desired behavior change. There is some

evidence that well-designed cognitive behavioral change interventions lasting at least one year are successful in supporting efficacious behavior. Although only five studies reported on the longer-term efficacy of their interventions and the maintenance of the outcomes, these Web-based interventions provide evidence that maintenance of long-term participation in Web-based interventions is possible in addition to being clinically beneficial.

Chapter 4. Using Longitudinal Mixed Modeling To Assess Concurrent, Multi-Symptom Change In Individuals With HIV/AIDS



ABSTRACT

Background: Muscle aches, numbness in the feet/toes (neuropathic), and fatigue are commonly ranked among the most frequently reported symptoms by individuals with HIV/AIDS, both those taking or not taking antiretroviral medications (ARVs), in cross-sectional studies. Longitudinal studies of symptom change over time and symptom synergies have not been examined in this population. Individual demographic characteristics are considered in their role in identifying the symptom trajectory in these individuals. **Methods:** A subset analysis from a six-month longitudinal sample of 243 HIV+ individuals taking ARVs was studied. The sample was 70% (n=169) male, 87% (n=212) non-white, mean age of 41.8 years (SD=7.6, range 22 to 68), HIV+ for a mean of 8.6 years (SD=4.60, range 1 to 22), with 51% (n=125) having an AIDS diagnosis, and 26% (n=64) reporting a depression diagnosis at enrollment. Multilevel, logistic regression models were used to analyze both lagged and concurrent effects of the time-varying covariates of self-reported muscle ache, numbness of the feet/toes, and fatigue. Various demographic characteristics were also analyzed for their effect on the symptoms intercepts and change over time. **Results:** There is consistency in the proportions of individuals reporting symptoms initially and the proportions remain constant over time. The lagged effects model showed that a report of numbness in prior periods is twice as likely to report fatigue in subsequent periods (OR=2.31, $p \leq 0.05$). In concurrent, multiple symptom models, at baseline, the odds of an individual reporting no additional symptoms and having fatigue is 0.13, an equivalent risk of about 12%. Individuals reporting numbness of the feet and toes are three times as likely to report fatigue. Reporting muscle aches increases the odds of fatigue by 16 (a 95% likelihood) over the six month

reporting period. Individuals having a prior medical diagnosis of depression were nearly four times as likely to report fatigue than those without a depression diagnosis.

Conclusions: In individuals with HIV/AIDS who are taking ARVs, there is evidence of symptom synergy in individuals with muscle aches and numbness increasing the initial status of fatigue reports. The simultaneous, multi-symptom occurrences of muscle aches, numbness in the feet/toes, and fatigue have an additive effect in increasing the levels of fatigue. These symptoms remain constant over time. This analysis provides evidence that symptom change in light of the presence of other symptoms can provide a more accurate representation of an individual's symptom experience. When evaluating patients with muscle aches, particularly with numbness of the feet and toes, an evaluation of fatigue should be considered. The consideration of treatment of multiple symptoms may provide improved patient outcomes over a single symptom approach to care.

INTRODUCTION

Understanding the course of symptoms in individuals with chronic illness such as diabetes, hypertension, HIV/AIDS, and in those undergoing chemotherapy for cancer, is a fundamental concern for clinicians and clinical researchers. Symptoms associated with HIV illness as well as the side effects of the anti-retroviral regimens (ARV's) used to prevent replication of the HIV virus have been associated with decreased HIV medication adherence (Ammassari et al., 2004; Bonfanti et al., 2001; Catz, Kelly, Bogart, Benotsch, & McAuliffe, 2000; Holzemer, 2002; Vogl et al., 1999) and decreased quality of life (Davis, 2004; Hudson, Kirksey, & Holzemer, 2004). Muscle aches, numbness in the feet/toes (neuropathy) and fatigue are commonly ranked among the most frequently reported symptoms by individuals with HIV/AIDS, both those taking or not taking antiretroviral medications (ARVs), in descriptive and cross-sectional studies. There are no longitudinal studies exploring these symptom experiences in individuals with HIV/AIDS. Many symptoms such as depression, anxiety, fatigue, and shortness of breath are often unrecognized by health care providers and are often under-treated (Hughes, 2004). These studies report that symptoms are transient by nature and vary in their presence, absence, and intensity. In particular, there are few published studies describing how these individuals experience of symptoms change in their presence or absence over multiple measurement periods.

Recent developments in symptom research in cancer and cancer treatment have produced results that are applicable to HIV symptom management research. In their seminal research of symptom occurrence in cancer, Dodd, Miaskowski and Paul (2001) found that symptoms do not occur alone but in groups, illustrating an adverse synergism

of multi-symptom occurrences in the symptom experience. These researchers identified a group of three or more concurrent symptoms as being an association of symptoms they termed symptom clusters (Dodd et al., 2001).

The hypothesis that symptoms may occur concurrently in groups was initially proposed in psychology and psychiatry, and subsequently has been widely used in these fields (Kim, McGuire, Tulman, & Barsevick, 2005). The concept of symptom clusters has long been the basis for disease classification and diagnosis of psychological disorders. In their structured review on the subject of symptom clusters, Kim and colleagues noted that symptom clusters were initially identified by clinical impressions and expert consensus, and later statistical methods as exploratory and confirmatory factor analysis were used for identifying symptom clusters, naming factors as symptom clusters (Dodd et al., 2001; Gift, Jablonski, Stommel, & Given, 2004; Gift, Stommel, Jablonski, & Given, 2003; Kim, McGuire, Tulman, & Barsevick, 2005; Miaskowski, Dodd, & Lee, 2004; Voss, Portillo, Holzemer, & Dodd, In press). Authors as Amdur and Liberzon proposed that separately, the clusters provide the basis for diagnosis and classification and in combination, well defined multiple symptom clusters may better conceptualize illness (Amdur & Liberzon, 2001). Consensus of what constitutes a symptom cluster or whether nor not a symptom cluster can exist is still unclear. However, in the case of cancer, there now appears to be consensus among researchers that multiple concurrent symptoms caused by cancer, cancer treatment, or both may be best studied by research focused on 1) how a set of symptoms are related; 2) how the multiple symptoms and their treatment are related and influence each other; and 3) how together, symptoms influence studied outcomes (Barsevick, Whitmer, Nail, Beck, & Dudley, 2006). Still, these focal

points of research do not explicitly take into account the symptom experience over multiple time periods and any additive effects in symptom frequency and/or intensity caused by the presence of multiple symptoms.

Recent physiological research shows that in patients living with HIV/AIDS and receiving ARVs, acute fatigue is a lead indicator for cellular mitochondrial dysfunction and, as a result acute fatigue onset and chronic fatigue may have differing physiological and psychological origins (Voss, 2005). Sensory neuropathy occurring in the context of HIV/AIDS is also a frequently reported symptom, particularly in patients treated with non-nucleoside reverse transcriptase inhibitors (NRTI) antiretrovirals zalcitabine (ddC, Hivid), stavudine (d4T, Zerit) and didanosine (ddI, Videx). Though decreasing in use in the United States, stauvidine is a component of the single pill combination treatment used in treating HIV in Africa. NRTI-sensory neuropathy presents as a length-dependent sensory neuropathy (i.e., feet affected first) manifested by pain in the soles of the feet in over 60 percent of individuals and paresthesias (numbness) in 40 percent. Sensory neuropathy not only affects the quality of life, but also is frequently under-treated, even by expert HIV providers. In addition, the development of neuropathic symptoms as well as the fear of sensory neuropathy, may reduce adherence with antiretroviral regimens (McArthur, 2001) . Finally, peripheral neuropathy may actually be an early marker of mitochondrial dysfunction, which is now believed to contribute to the development of lipodystrophy/fat redistribution, lactic acidosis, and other toxicities.

Research by Cleeland et al (2003) on the symptoms related to cancer and cancer treatment including pain, wasting, fatigue, cognitive impairment, anxiety, and depression describe biologic pathway similarities between such symptoms and sickness behavior.

describe biologic pathway similarities between such symptoms and sickness behavior. The findings suggest that the physiological and psychological responses are mediated by cytokines acting on the central and peripheral nervous systems inducing sickness behavior in human and animal models. Administering cytokine antagonists often prevented the symptoms from occurring (Cleeland et al., 2003).

Franceour (2005) brings evidence from longitudinal research in depressive affect and bone pain associated with the synergistic interactions of fever, fatigue/weakness, decreased appetite, and weight loss in individuals with cancer receiving palliative radiation treatment. Using dichotomous variables representing a symptoms presence or absence, this research found that significant overlapping interactions between pain and nausea, and pain with dyspnea might be in part due to clustering of symptoms associated with fatigue and depression. Further analysis of these variables suggests heightened pain sensitivity in individuals having concurrent symptomology with depression and is related to crossover effects of shared pathways and reporting the improvement in pain as a result of fatigue and depression interventions (Francoeur, 2005).

Quantitatively characterizing symptoms and symptom occurrence over time can help clinicians and researchers elucidate the underlying heterogeneity in individuals that are relevant to symptom change. Understanding individual differences in reported symptom frequencies and intensity of the symptoms are important to health care providers in helping their patients in the management of symptoms helping in adherence to medication/treatment regimens and other desirable outcomes.

METHODS

This analysis provides a first stage approach to identify if multiple symptoms occur in synchrony with fatigue. Further, this research seeks to determine whether the presence or absence of additional symptoms change the proportion of fatigue occurrence and to quantify the likelihood of change in the occurrence of fatigue. Longitudinal, repeated measures data are used to describe changes in fatigue over time, examine predictors of fatigue, and to assess the impact of other symptoms on fatigue.

Design

A subset analysis from a six-month longitudinal randomized controlled trial of 243 HIV+ individuals taking ARVs was studied for the effectiveness of tailored nursing intervention to increase adherence to ARVs (Holzemer et al., 2006). The study showed no significant difference in outcome of adherence between the treatment and control groups. Self-reported symptom frequency and intensity measure were obtained at baseline (month 0), one month, three months, and six months. Multi-level mixed growth models using Mplus (Muthen & Muthen, 1998 - 2006) were used to assess single and multiple symptom models for the symptoms of self-reported numbness, muscle ache, and fatigue associated with HIV illness.

Instruments

Two instruments from the study were used in this subset analysis of symptoms. These instruments were completed by the participant at baseline (at time of randomization into the study), and at one-month, three-month, and six month intervals thereafter. They included a demographic questionnaire and a checklist of symptoms for persons with HIV. The *Demographic Questionnaire* was used to obtain demographic

data from the participants. The *Revised Sign and Symptom Checklist for Persons with HIV Disease (SSC-HIVrev)* consists of 72 items, that measure symptom experience. Respondents select only those symptoms experienced in the past 24 hours. Response choices include "mild", "moderate" or "severe" for symptom intensity. The symptoms not experienced are coded zero "no symptom" (Holzemer, Hudson, Kirksey, Hamilton, & Bakken, 2001).

Choosing multi-level growth modeling over other methods

Multi-level growth mixture modeling is well suited to analyze symptom data as it assesses each individual intercept and growth trajectory and estimates the individual deviance from the group average. The method does not require equal waves of data as in repeated measures analysis of variance (ANOVA) and multivariate analysis of variance (MANOVA), making it appealing for longitudinal analyses where participant attrition is often a problem in maintaining a meaningful N and to retain power in statistical analyses. When the outcome variable of interest is measured from the same subject repeatedly over time, the measurements are almost always correlated in some way. To account for this correlation, repeated measures statistical analysis tools may be used to make inferences (Ugrinowitsch, Fellingham, & Ricard, 2004) The more traditional ordinary least squares (OLS) computational methods used by repeated measures ANOVA, etc., assumes a constant correlation among multiple measurements within a subject. This assumption would be true if measurements taken closer in time have correlations similar as those taken farther apart in time. However, the assumption of constant correlation for measurements within a subject may not be true in many cases and correlations grow smaller over time. The multilevel mixed models use an estimation algorithm called

generalized least squares (GLS) that is designed to deal with correlated data. Instead of comparing means across treatments and time points, and dealing with complex interpretation of the model interaction terms, growth trajectories test for differences in initial values and in rates of growth of each factor's levels, allowing for a more straightforward interpretation of data. The results obtained from these statistical analyses are very useful to explain the effects of change incurred as a result of an intervention.

Levels of the multi-level models in this analysis

The first stage of a multilevel model of change, *level-one*, (individual change over time) focuses on within-individual change over time. The individual pattern of change over time is described for each person's individual trajectory. The goal of a level-one analysis is to describe the shape of each person's individual trajectory as being linear or nonlinear and consistent or fluctuating. The second stage of an analysis of change, known as *level-two*, is focused on between-individual differences in change. Patterns of within-individual change are assessed to detect heterogeneity in change across individuals and to determine the relationship between predictors and the shape of each person's individual trajectory.

In this analysis, the level-one analytical focus was on the symptoms of muscle aches, numbness in the feet/toes (neuropathy), and fatigue. The categorical symptom variables had non-normal distributions. Each symptom variable had a preponderance of zeros (no symptom) and symptom intensities were rated mild or moderate in nearly 75% of the cases. Because of the non-normal distributions, these symptom variables were recoded into dichotomous variables with binomial distributions. To achieve this, the response choices of 1, 2, and 3, were all recoded as 1 "yes". The zero was retained as a

"no" response. These dichotomous variables were analyzed using multilevel logistic regression.

Binomial (or binary) logistic regression is a form of regression that is used when the dependent is a dichotomy and the independents are of any type. Logistic regression applies maximum likelihood estimation after transforming the dependent into a logit variable (the natural log of the odds of the dependent occurring or not). In this way, logistic regression estimates the probability of a certain event occurring.

The multilevel model using dichotomous data is modified from the traditional format (Snijders & Bosker, 1999), and provides an application using the multilevel model. In all models the assessment of the level of influence each symptom had upon one another was assessed by comparison of the fit between a model that held the parameter intercepts constant (constrained model) and a model that allowed the intercepts to be random (unconstrained model). The constrained model limited the intercept to a single averaged value of the intercepts for each parameter. The model fit statistics were compared for differences. If the two models did not greatly differ in their fit statistics, then the modeled parameter estimations of the constrained models reflect the changes in the dependent outcome of fatigue that results from the effects of the independent symptom variables. If the models differ in their fit statistics, then there were other non-measured influences on the fatigue outcome.

Assessment For Temporal Symptom Occurrence

Lagged effects linear growth models were assessed to determine if a temporal relationship exists between the symptoms of numbness, muscle aches and fatigue. These models assessed fatigue occurrence as the outcome variable dependent upon the presence

or absence of muscle aches and/or numbness in prior time periods. The models measured the individual and average intercepts and slope changes. The models were evaluated for correlation among the observed variables and the unobserved (latent) variables. In addition, correlation among the residual, comprised of the unexplained measurement error from both level one and level variables was evaluated (Figure 4.1).

[Figure 4.1 about here]

The second set of models assessed the concurrent symptom status of muscle ache and numbness and their association with the outcome of fatigue (Figure 4.2). This model was further assessed further by the addition of level-two characteristics of the individuals including age, gender, having and AIDS diagnosis, and having a medical diagnosis of depression at the time of study enrollment. These variables helped explain any between-person differences in trajectories of the level-one time-varying symptom covariates. It was assumed that would be differences between individuals that were not captured by the explanatory variables and are regarded as unexplained variability with the set of all participants.

[Figure 4.2 about here]

RESULTS:

There was a total sample size of 240 individuals with the potential of four observations each at baseline, month 1, month 3, and month 6. The multi-level analysis is based on a total of 825 observations. The demographic variables revealed that the sample was 70% (n=169) male, 87% (n=212) non-white (72.4% African American, 10.7% Hispanic), mean age of 41.8 years (SD=7.6, range 22 to 68), HIV+ for a mean of 8.7 years (SD=4.7, range <1 to 22), with 51% (n=125) having an AIDS diagnosis, and

26% (n=64) reporting a depression diagnosis at enrollment (Table 4.1). There were no differences in symptom frequency or in the report of depression between the primary study's treatment and control groups. The mean intensity of the symptoms of fatigue, muscle aches, and numbness of the feet/toes ranged from 1.7 to 2.1 for all the measurement periods on a scale of one to three. For all three symptoms, reports of severe symptom intensity were highest at baseline, decreased to the month three measurement period then increased slightly at month six. Over time, there is a decrease in the reports of fatigue and numbness, and a slight increase in muscle aches (Table 4.1).

[Table 4.1. about here]

Symptom growth models

The Single symptom growth model

The initial model to assess symptom change looked at the initial estimates of fatigue and fatigue change over time without additional variable influence (Table 4.3, model A.). This fatigue intercept for this model revealed the odds of reporting fatigue was .80 (23% less than those not reporting fatigue), validating that most cases at baseline reported not having fatigue as noted in the frequency Table 4.1. There was significant variation in the fatigue intercepts and relatively large standard errors (SE) indicating that there are other non-explained influences on the fatigue symptom intercepts contributing to individual variation in this single symptom model.

The slope of fatigue was generally flat (OR=1) indicating no change over time. This is again substantiated by the covariance between the intercept and slope having a logit value close to zero meaning slope did not greatly vary as the intercept values varied. There is no significant residual variance in either the intercept or the rate of change

indicating the amount of scatter about the individuals observed outcome changed very little over the six-month period. Again, suggesting that there is consistency in the proportions of individuals reporting fatigue initially and that the proportions remain constant over time. The relatively large standard errors about the average trajectories indicate a great deal of individual variation of change over time.

Lagged Effects Linear Growth Model

To assess the lagged effect of symptom occurrence over time, and any additive effects of additional symptoms, individual models estimating the first effect of muscle aches on fatigue and then estimating the effects of numbness of the feet/toes on fatigue were developed. This was followed by the development of a model that estimated the effect of both symptoms simultaneously on the outcome of fatigue. The level of symptom correlation between time periods was consistent as was the relative magnitudes of the correlations between the symptoms. These correlations ranged from .44 to .60 for fatigue with muscle aches; .20 to .42 for fatigue with numbness; and .21 to .34 for muscle aches with numbness (Table 4.2). In all these models, there were no significant differences in the fit indices between the constrained and unconstrained models indicating that the constrained model represents the data well in estimating the effects of the symptoms on fatigue.

[Table 4.2. about here]

A significant relationship between muscle aches and fatigue intercepts was noted in the six-month measurement period (OR=1.8, $p \leq 0.05$). Significant relationships between numbness and fatigue were also noted for the entire measurement period (OR=.2.7, $p \leq 0.05$). Next, a combined model estimating the effect of both muscle aches and numbness on fatigue was developed (Table 4.3, model B.). This significant relationship between muscle aches and fatigue is no longer significant (OR=1.21, $p > 0.05$). This model showed a continued significant effect of numbness on fatigue (OR=2.48, $p \leq 0.05$). This indicated a temporal relationship between numbness and the report of fatigue in this sample over the six-month time period.

Interactions between each level-one symptom variable and time were estimated as the product of the symptom and the variables of time for each time period. These product variables were included in the regression models. No significant interactions between symptoms and time were noted, indicating that in the lagged-symptom models, the presence of fatigue did not change as a result of the effect of time alone. The addition of the level-two variable "having a depression diagnosis" did not impact the mean intercepts for any of the symptoms and also was not a significant parameter in this model. There was also no interaction effect between having a depression diagnosis and any of the symptoms and was not a significant parameter in this model.

[Table 4.3 about here]

Concurrent Symptom Growth Model

As in the lagged-effect models, in order to better assess whether or not other non symptom-related factors were contributing to the individuals symptom trajectory change of fatigue, the constrained and unconstrained models were estimated. Comparison of the constrained and unconstrained models for single-symptom models for fatigue, muscle ache, and numbness revealed no significant differences (X^2 difference < 15) between the respective models (fatigue $X^2= 0.346$, $p \geq 0.05$; muscle ache $X^2= 2.19$, $p \geq 0.05$; numbness $X^2=1.90$, $p \geq 0.05$).

In all models, the analysis of the fatigue slope change included linear, quadratic and cubic estimates. The linear slope measures only were reported for fatigue and numbness since the quadratic and cubic slope change estimates were not significant in any model. None of the slope estimates was significant. Additionally, the linear slope

parameter generally provided the best estimate of fit over time as indicated by a smaller standard error and higher Z score than the non-linear estimates.

As in the lagged effect models, interactions between each level-one symptom variable and time were estimated. In the concurrent models there were no significant interactions between symptoms and time. Again, the level-two variable indicating a medical diagnosis of depression at baseline was also tested for interaction with fatigue, muscle ache, and numbness over time. These estimations did not identify an influence of a depression diagnosis on an individuals' report of fatigue over time.

Level-Two Model Characteristics

At level two, the specified relationships between the individual growth parameters and the person level predictors were estimated in an incremental process adding the additional level 2 variables of years living with HIV, age, having an AIDS diagnosis, race - defined as white/nonwhite, and other medical diagnosis of depression in each subsequent run.

Analyses of these fixed effects in the multi-symptom model showed only depression was a significant predictor of fatigue, increasing the odds of fatigue by 3.6 (Table 4.3, model E. In the multiple symptom models, at baseline, the odds of an individual reporting no additional symptoms and having fatigue is 0.13, an equivalent risk of about 12%. Individuals reporting numbness of the feet and toes are three times as likely to report fatigue. Further, individuals reporting muscle aches are 17 times as likely to report fatigue.

Comparison of the concurrent and lagged models

Both the concurrent and lagged symptom models showed significantly improved intercept variance parameters from the fatigue only symptom model with the addition of the time-varying covariates. In the concurrent model, 15.4 % of the variance in individual intercepts was explained and, including the level-two variable of a depression diagnosis, 30% of the variance in individual intercept values was explained. There was still unexplained variation in the intercepts however. The multi-symptom lagged effects model explained 41% of the variance in individual intercepts. The difference between the amount of explained variance suggests that the reported symptom change in fatigue between baseline and time one contributes to a large extent to the individual intercept variation.

There was a small change in the fit statistics of the log likelihood, Akaike information criterion (AIC) statistic and Bayesian information criterion (BIC) statistic. The fit statistics of both the lagged and concurrent models improved (values closer to zero) with the addition of symptoms and again, with the addition of the level two variable of a depression diagnosis. The concurrent models fit statistics were larger as they were fitting four time periods of data simultaneously. Whereas the lagged models were fitting only three time periods of data. Because of the parameter measurement differences between these two set of models, a direct comparison of variation and fit between the lagged and concurrent models is not reasonable.

DISCUSSION

This analysis provides evidence that the multiple symptoms of fatigue, muscle aches, and numbness of the feet/toes do impact one another and the level of effect is quantifiable. The significant between-symptom correlations at each measurement period

confirm that these symptoms are commonly reported together. The consistency of the level of symptom correlations between time periods and the consistent relative magnitudes of the correlations between the symptoms provided an opportunity to further investigate both the temporal and concurrent effects these symptoms may have upon one another. The models that included the identified multiple symptoms helped explain the unmeasured variation in fatigue estimated in the initial growth model

Lagged Effects Linear Growth Models

The longitudinal study of symptoms can serve to provide valuable information as a source of data for establishing a baseline trend of information. This subset analysis was a review of symptoms and symptom occurrence over time for which there was no intervention in the design of the study to address symptom status. The short time [six-month] period of measurement may preclude any measurement of variability of symptom change. Also, the time between measurement periods may also have altered the time varying influence between symptoms.

Concurrent Symptom Growth Models

The simultaneous, multi-symptom occurrences of muscle aches, numbness in the feet/toes, and fatigue have an additive effect in increasing the levels of fatigue. The odds value of 0.80 for individuals reporting fatigue alone translates into a relative risk of about 45%. The odds increase to 7.96 times as likely to report fatigue (relative risk about 95%) in individuals concurrently reporting numbness and muscle aches. In the model with fatigue, muscle ache, and numbness combined, individuals having a prior medical diagnosis of depression were over three times as likely to report fatigue than those without a depression diagnosis.

The difference between the amount of explained variance between the concurrent and lagged effects models suggests that the reported symptom change in fatigue between baseline and time one contributes to a large extent to the individual intercept variation model. This may indicate that the change from the initial self assessment of fatigue at time one was significantly greater than in the subsequent measurement periods. This occurrence is substantiated by the frequency of fatigue measured at baseline and time one.

The models do not fully address the role of prior symptom status of fatigue as an outcome variable and its role is predicting ongoing fatigue. Longitudinal data sets with larger sample size are needed to assess the autoregressive nature of prior symptom status to predict future symptom status in conjunction with change over a substantial period of time. It was determined that once observed, symptom presence changed very little over the six-month evaluation period, in the absence of any intervention. It is therefore not unexpected that symptoms did not change over time. Further, the use of dichotomous data is limiting but in light of limited count data that contain a preponderance of zeros (no symptom), the methods to assess symptom change over time, produced plausible models.

Researchers are now actively involved in studies that invoke the need for longitudinal multi-level models of change over time. In 2004, the National Institute of Nursing Research (NINR) announced plans for the support of research for the simultaneous management of multiple symptoms. The NINR supports research that identifies and describes groupings of symptoms in individuals with HIV/AIDS and cancer by determining the effects of these symptom clusters on the individual, and developing interventions to manage the multiple symptomology (Grady, 2004). The results from longitudinal analyses of symptom change over time provide further evidence of symptom synergism in individuals with HIV/AIDS. These symptoms include

both the psychosocial symptom of fatigue and the physical symptoms of numbness of the feet and toes and muscle aches. Studies incorporating mixed modeling for the effects of time-varying symptom covariates offer additional understanding of the role of symptom experience in these individuals and provide insights into how symptoms group together and the effects of patient interventions and treatment for multiple, concurrent symptoms.

Since the early 1990's the Internet has been used as a conduit to provide health information to patients and as a forum for behavior change health interventions. However, the rigor of the interventions in their theoretical underpinnings and the expectations of the interventions to provide sustainable longer-term outcomes have not been addressed. This is in part due to inadequate research methods and costly resources to provide the structure necessary to repeatedly measure individuals over longer multi time periods. The aggregate efficacy of Web-based intervention methods and instruments has not been adequately assessed in comparative Web-based interventions to non-Web-based interventions such as traditional face-to-face interactions and paper and pencil assessments.

In order to ascertain the utility, efficacy, and efficiency of the Internet to provide ongoing assessments obtaining measures over multiple time periods three research projects were undertaken over a three year period to address the overarching questions of rigor and equivalency of Web-based to non-Web based behavior change interventions and also to determine the best statistical methodology to assess change in dichotomous and/or ordinal outcome measures. The research projects focused on comparing the efficacy of Web based to non-Web based intervention outcomes for the same behavior/knowledge change outcome and analytical strategies t examine change over time.

Changes in behavior, have been empirically tested in many studies, providing evidence claims to support positive outcomes for theoretically based programs in varying chronic illnesses. The behavior change occurs through enhancing an individuals belief in his /her own ability to change their behavior to achieve a goal. These abilities lead to the

growth of a participants' self-confidence to manage illness- and treatment-related symptoms. Understanding motivational influences to encourage and maintain behavior change is important to maintain the desired effects often reported to have been achieved by behavior change interventions.

This research project revealed that behavior change can be effectively administered incorporating Web-based interventions and that such interventions are at least as effective and in fact, moderately more effective, than traditional face-to-face and paper based behavior change interventions. The effectiveness was demonstrated through a meta-analytic literature review finding that 16 of the 17 outcomes revealed improved knowledge and/or improved behavioral outcomes for participants using the Web-based interventions. The individual effect sizes for each of the reviewed study variables for knowledge change and/or behavioral change showed effect sizes ranged from small (±.01 to .19), moderate (±.20 to .47),and moderately large (.54 to .75). The comparison of the reliability of instruments used in a Web based format to traditional formats was done showing no significant difference in the format used to administer the instrument.

Web based utilization provides measurement methods that can ascertain the use of a Web site, visits to a various pages on the site, and paths to trace links and usage patterns by the user. These are added benefits to using the Internet in administrating an intervention and useful to determine the dose of the Web-based intervention. Based on the individual's response, how much intervention that is needed by an individual can be tailored and varied. The burden to complete the needed information throughout the site may be relieved by increased interactivity to create and maintain interest in the site. Interactivity may help reduce attrition of Web users and provide benefits in producing

positive behavioral change. The two web-based reviews revealed that interactive Web-based intervention and maintenance programs to be useful as mechanisms to achieve ongoing repeated measurement for the study of process and outcome variables. These studies find that longitudinal study design should include the expectation of a loss of about one-fourth of the participants over time.

In both of these structured analyses, there were no significant differences between the length of an intervention and effect size for the studied outcome. The research question regarding the typical length of an intervention/maintenance study to date and whether or not one can make the inference that such time-limited intervention do actually change behavior was studied in the structured review on the use of theoretical models in Web based Interventions. The results show evidence that well-designed cognitive behavioral change interventions and maintenance programs lasting at least one year are successful in supporting efficacious behavior.

Longitudinal assessments are useful and practical in understanding how symptoms occur synergistically as well for the assessment of adequate interventions to alleviate or prevent adverse symptom occurrence in the presence of chronic illness. In chronic illness, symptoms themselves are often transitory, with individually moderating influences that impact an individual's perception of intensity, impact, and degree of bother. A secondary analysis of the symptom experience in 243 HIV-positive individuals taking antiretroviral medications was performed to assess the measurement of change in longitudinal repeated-measures models. Longitudinal mixed models was used to estimate outcome change over time to assess the feasibility of the statistical method as a framework for ongoing longitudinal analysis of data collected in a Web-based

intervention. Results from the longitudinal analysis of symptom change over time make clear that a model measuring only one symptom over time with or without covariates is not adequate to estimate the synergistic effects of other symptoms. Analysis in symptom change in light of the presence of other symptoms can provide a more accurate representation of an individual's symptom experience.

Study of the multi-symptom occurrences of fatigue, muscle aches and foot/ toe numbness substantiate evidence for symptom synergism in individuals with HIV/AIDS. Future study in symptom research in HIV/AIDS and other chronic illnesses require studies incorporating longitudinal design and multi-level analytical methods to capture the heterogeneity in individual change trajectories. However, to more fully utilize these longitudinal methods, the limitations of statistical analysis to adequately model categorical count or dichotomous data must be addressed. Shortcomings in these statistical methods to address ordinal data changes over time suggest that measures need to be increasingly variable and scalar in nature. As a result, revised instruments are needed and validation of these revised instruments is needed.

The use of the Internet to provide Web-based interventions has been proven to be a valid and reliable modality for presenting information and support to users. Although Web-based interventions have the potential for maintaining participation of individuals at a low marginal cost, maintaining the participant's interest in the ongoing use of the intervention over an extended period of time is needed. Benefits to be gained from the use of Web-based behavior change interventions can be anticipated as nearly all the identified studies noted significant statistical and/or effect size results for one or more of their studied outcome change variables. The identified models reveal evidence that

interventions and behavior change maintenance both explicitly or implicitly guided by cognitive behavioral theoretical models in Web-based interventions improve an individual's behavioral change. These studies should also include theoretical constructs using models that explicitly target measures of an individual's behavioral intention and interest in an intervention at the outset of an intervention study with repeated measurements over the course of the intervention.

To appropriately assess changes due to an intervention, the adequate and repeated measurement of symptom occurrence and intensity needs should be obtained from a trended baseline. This trended baseline can be applied to ongoing longitudinal assessments of many different and potentially time-varying data. A systematic plan incorporating a trended baseline assessment, will include an individuals self assessment and self care of symptoms associated with illness as well as quality of life data that is to be regularly captured via the designed interactive self care symptom management checklist and symptom management strategies. The measures are assessed for multiple phases including the intra-intervention phase as well as post intervention maintenance phase monitoring.

The management and measurement of any chronic disease should be personalized to an individual, as the person is ultimately responsible for the success of the intervention evidenced by maintenance of the behavior change. Self-management of a chronic condition and contribution to disease management has demonstrated improved results and adherence to treatment regimens. Web-based interventions should be designed to allow individuals to tailor the intervention to his or her specific needs. With the advent of high-level Web programming languages, intended to provide effective data and information

provision and retrieval, the flexibility to provide interactive and responsive programs for use on the Internet is increasing. This is conducive to the incorporation of interactive and continuous self-monitoring, feedback and information exchange that is certain to play an increasingly important role for this patient care need.

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TABLE 2.1. INCLUSION AND EXCLUSION CRITERIA FOR THE META-ANALYSIS

Inclusion Criteria:
• Publication date: January 1996 to December 2003.
• Comparison of a Web-based behavior or educational intervention, intended to influence behavioral change and/or self-efficacy health outcomes of participants compared to a non-Web-based method.
o Either randomized and controlled clinical trials or convenience samples
o Descriptive studies using a baseline and post study score(s)
• Clinic and clinic/home based studies
• Score of 12 or more on the Quality Rating Scale for the study (see Table 2).
Exclusion Criteria:
• Publication date: prior to January 1996
• Excluded studies:
o Non-Web-based Computer Assisted Instruction (CAI) studies
o Procedural methods citations (methods papers, non-implemented studies)
o Prospective non-implemented studies/citations
o Provider focused studies, no client participation
o Web site access only studies
o Professional practice studies
o Telephone based interventions
o Remote monitoring studies
o Interventions incorporating synchronous video communication
o Web-based intervention compared to another Web-based intervention
o Classroom or non-clinic/non-home location
• Score less than 12 on the Quality Rating Scale for the study (see Table 2).

TABLE 2.2. QUALITY EVALUATION OF SELECTED INVESTIGATIONS

Study Characteristic	Evaluation Criteria	Scoring
Study Design	1. Randomized trial 2. Non-randomized trial with control group 3. Descriptive/cohort study	3 points 2 points 1 point
Selection and specification of the study sample	1. Random selection with description of 4 to 5 demographic variables 2. Random sampling without sufficient description of the demographic variables 3. Convenience sampling with sufficient background information 4. Bonus point for a description of how many patients were excluded and reasons for exclusion.	3 points 2 points 1 point + 1 point
Specification of the illness/condition	1. Illness specified with reproducible inclusion/exclusion criteria. 2. Diagnostic criteria only were provided 3. Diagnosis only 4. Bonus point if all prior criteria were met and co-morbidities were described.	3 points 2 points 1 point +1 point
Reproducibility of the study	1. Description permits the reader to replicate the study 2. Results provided a standard for computing effect size (i.e., variable means, standard error, or standard deviation correctly stated).	1 point Yes: 3 points No: 0 points
Outcomes specification and measurement	1. Outcome measure is described and valid instrument use was clearly provided 2. Outcomes were not measured using valid and reliable instruments 3. Results did not match the described outcomes to be measured in the study	3 points 2 points -1 point
Maximum score		18 points

Only studies that scored 12 or higher were retained for meta-analysis

TABLE 2.3. SUMMARY OF REVIEWED STUDIES

Author(s) And date	Intervention Focus	N and study Characteristics	Conceptual Framework	Design	Variables/Behavior Change Variable	Study Findings	Reliability of Effect Variable Instrument
Clarke G, Reid E, Eubanks D, O'Connor E, DeBar LL, Kelleher C, Lynch F Nunley S, 2002	Depression	N = 299 (I = 144, C = 155) 32-week study evaluating the effectiveness of a Web-based psycho educational tutorial intervention to reduce depression	Cognitive restructuring techniques	Longitudinal, Randomized study Repeated measures	IV = Intervention using tailored self-management or peer support therapy using cognitive therapeutic techniques DV = CESD depression score change	No significant differences for the Internet program across the entire sample. Post-hoc, analyses revealed a modest effect among persons reporting low levels of depression at intake.	CES-D 20-statement scale. Internal consistency from 0.85 to .90. Concurrent validity with Beck depression inventory, brief screen for depression.
Krishna S, Francisco BD, Balas A, Konig P, Graff GR, Madsen RW, 2003	Asthma Education	N = 228 (I = 121, C = 107) 52-week intervention comparing the use of IMPACT, an Internet enabled interactive asthma education program, to printed and verbal asthma education in a pediatric population, 18 years or younger.	Knowledge change leading to behavior change	Longitudinal, Randomized study Repeated measures	IV = Use of IMPACT, Web-based intervention DV = Children's asthma knowledge, Caregivers asthma knowledge, days of asthma symptoms, medication use, ER /urgent care visits, missed school days, hospitalizations	Knowledge change was a primary indicator for program use and effectiveness. Multimedia education is a feasible adjunct that can be incorporated into a clinic visit. Increased asthma knowledge, decreased morbidity, and reduced use of ER services in IMPACT participants.	50-item asthma knowledge survey, 10 item asthma scenario survey. No validity or reliability documentation.
Celio AA, Winzelberg AJ, Wilfley D, Eppstein-Herald D, Springer EA, Dev P, Barr-Taylor C, 2000	Eating Disorders	N = 76 (Internet-student bodies (SB) = 27, Class (BT) = 25, wait-list/control (WLC) = 24) 8-week intervention and four-month follow up. Comparison of Web-based and classroom based psycho educational interventions to reduce body dissatisfaction and eating disorders/behaviors/attitudes.	Behavior change	Longitudinal, randomized study Repeated measures	IV = Web-based intervention, Class room intervention DV = Change in body satisfaction questionnaire scores, Eating disorder examination questionnaire, EDI-Drive for thinness scale.	Internet intervention had a significant impact on reducing risk factors for eating disorders. No significant effects were found between the BT and WLC conditions	Body satisfaction questionnaire (BSQ) has internal consistency of .97, test-retest validity = 0.88, and concurrent validity coefficient = .66. At baseline measures, the EDE and BSQ showed spearman correlation = .86.
Harvey-Berino J, Pintauro S, Buzzell P, DiGiulio M, Casey-Gold B, Moldovan C, Ramirez E, 2002	Weight Control	N = 46 (Internet Support IS = 15, Traditional Support TS = 14, Control = 15) Web-based study, investigating the effectiveness of a weight maintenance program conducted over the Internet compared to in-person sessions. A 6-month clinical behavioral weight loss trial with in-person behavioral obesity treatment followed by a 12-month maintenance program conducted both in-person (frequent in-person support; F-IPS, minimal in-person support; M-IPS) and over the Internet.	Not discussed	Longitudinal, Randomized, 12 month maintenance program study	IV = use of Internet support method DV = body weight, dietary intake, energy expended in physical activity, attendance, self-monitoring, comfort with technology Behavior change exhibited by attendance in weight loss meetings	Attendance was lower in the Internet condition over the 12 months of maintenance than in the F-IPS condition. After 6 months, many in the IS want to meet face-to-face. The IS condition gained significantly more weight than the F-IPS group during the first six months of weight maintenance	No validity or reliability of assessment instruments was documented.

TABLE 2.3. SUMMARY OF REVIEWED STUDIES (CONTINUED)

Author And date	Intervention Focus	N and study Characteristics	Conceptual Framework	Design	Variables/Behavior Change Variable	Study Findings	Reliability of Effect Variable Instrument
Oenema A, Brug J, Lechner L, 2001	Nutrition	N = 198, (I = 96, C = 102) Web-based tailored nutrition education program.	Weinstein's Precaution Adoption Process	Randomized trial Repeated measures (pre-post)	IV = Use of Web-based tailored nutrition education program DV = Validated food frequency questionnaire Behavior change exhibited by self report of awareness of personal dietary intake levels	Significant differences in awareness and intention to change were found between the intervention and control group at post-test. Tailored intervention was appreciated better, rated as more personally relevant, had more subjective impact on opinion and intentions to change than the general nutrition information.	Pearson correlations of about 0.7 for adults and 0.6 for adolescents were observed between fat scores derived from the Fat list and total and saturated fat intake in grams estimated by the 7-day diet records.
Harvey-Berino J, Pintauro SJ, Buzzell P, DiGiulio M, Gold BC, Moldovan C, Ramirez E, 2002	Weight Loss Maintenance	N = 122 (Internet = 40, Minimal in-person support = 41, Frequent in-person support = 41) Sustained contact following a weight loss program	Not discussed	Longitudinal 18 month weight maintenance program	IV = Use of Internet support method DV = body weight, dietary intake, energy expended in physical activity, attendance, self-monitoring, comfort with technology Behavior change exhibited by 18 mos. weight loss maintenance.	Internet group reported increased peer support. Internet support not as effective as minimal or frequent intensive in-person therapist support for facilitating the long-term maintenance of weight loss.. Weight loss did not differ by condition during treatment The IS condition gained more weight than the F-IPS group during the first 6 months of weight maintenance and sustained lesser weight loss than control.	No validity or reliability of assessment instruments was documented.
Chou FY, 2003	HIV/AIDS	N = 357 (I = 122, C = 237) Self Care Symptom Management in individuals living with HIV/AIDS (SSC-HIVrev.)	Behavior Change	Convenience sample (Web version)	IV = Use of Wed-based version of symptom reporting tool DV = Help seeking strategies, personal network, information resources, Use of medications	Dissertation, participants in Web group reported decreased help seeking strategies, decreased spiritual strategies, and decreased personal networks compared to non-Web-based responders.	SSC-HIVrev. Part 1- 45 HIV-related symptoms cluster into 11 factor scores. Reliability .76 - .91; Part 2- 19 HIV-related symptoms that do not cluster into factor scores but may be of interest from a clinical perspective; Part 3- 8 items related to gyn symptoms for women. Cronbach's alpha = .94.

TABLE 2.3. SUMMARY OF REVIEWED STUDIES (CONTINUED)

Author and date	Intervention Focus	N and study characteristics	Conceptual framework	Design	Variables/Behavior Change Variable	Study Findings	Reliability of Effect Variable Instrument
Marshall AL, Leslie ER, Bauman AE, Marcus BH, Owen N, 2003	Physical Activity Promotion	N = 655 (I = 327, C = 328) Eight week mediated physical activity Web-based intervention vs. eight week print based intervention	Trans-theoretical (stages of Change) Model	Longitudinal Randomized study	IV = Use of Web-based mediated physical activity (Active Living) intervention DV = Change in physical activity measured by the International Physical Activity Questionnaire (IPAQ) Short Past 7-day instrument.	Increase in total physical activity in the Print participants who were inactive at baseline. Decrease in average time spent sitting on a weekday in the Web group. No difference between Print and Web program effects on reported physical activity. The Print group showed slightly larger effects and a higher level of recognition of program materials.	No documentation of data supporting validity or reliability.
Gustafson DH, Hawkins RP, Boberg E, Pingree S, Serlin RE, Grazino F, Chan CL, 1999	HIV/AIDS	N = 204,(I = 94 overall, C = 89) The Comprehensive Health Enhancement Support System (CHESS) developed for HIV/AIDS) Received system for 3 or 6 months; controls received no intervention of the CHESS system.	Behavior change	Longitudinal Randomized trial, Repeated measures Pre, intra, and post	IV = Use of CHESS system DV = QOL variables (MOS short form) Hospital resource utilization Behavior change exhibited by level of participation in healthcare	Intervention group had shorter ambulatory .care visits, more phone calls to providers, fewer & shorter hospitalizations compared to control during the computer implementation period. Post-implementation no difference in number and length of hospitalizations. Use of non emergency/ emergency were not significantly different between groups	Four subscales from the MOS 36, Physical function (α=0.87), cognitive function (α=.91), energy (α=0.85), depression (α=0.90)
Christensen H, Griffiths KM, Korten A, 2002	Cognitive Behavioral Therapy	Web-based sample of 1096 completed the Goldberg depression scale. Subanalysis also includes 51 students enrolled in an Abnormal Psychology course and local population survey of 2385 20-24 year olds Free access to MoodGYM Web intervention	Cognitive behavioral change	Descriptive Study	IV = Use of MoodGYM DV = Changes in depression and anxiety symptoms	20% of sessions lasted > 16 mins. Those who completed at least 1 assessment reported initial symptoms of depression and anxiety that exceeded those found in population-based surveys and those characterizing a sample of University students. Both anxiety and depression scores decreased significantly as individuals progressed through the modules	Goldberg Depression and anxiety Scales The full set of nine questions need to be administered only if there are positive answers to the first 4. When assessed against the full set of 60 questions contained in the psychiatric assessment they have a specificity of 91% and a sensitivity of 86%

TABLE 2.3. SUMMARY OF REVIEWED STUDIES (CONTINUED)

Author and date	Intervention Focus	N and study characteristics	Conceptual framework	Design	Variables/Behavior Change Variable	Study Findings	Reliability of Effect Variable Instrument
Ritterband LM Cox DJ Kovatchev B McKnight L Walker LS Patel K Borowitz SM Sutphen J, 2003	Pediatric Encopresis	N = 24 (I = 12, C = 12) 3-week intervention for pediatric bowel training (Enhanced Toilet Training-ETT) to reduce defecation accidents called U-CAN-POOP-TOO. Evaluate the Internet version to overcome barriers of healthcare professional implementation of therapy alone.	Behavior change	Longitudinal study	IV = Use of Web-based U-CAN-POOP-TOO intervention for ETT DV = Reduction in number of defecation accidents, bathroom use change, encopresis knowledge questionnaire (EKQ), Virginia encopresis /constipation appreciation test (VECAT)	The Web participants showed improvement in reduced fecal soiling, increased toilet use, increased unprompted trips to the toilet. Both groups showed improvements in knowledge and toileting behaviors. "Internet interventions may be an effective way of delivering sophisticated behavioral interventions to a large and dispersed population in a convenient format."	VECAT- consists of 18 pairs of drawings (9 pairs of bowel-specific and 9 parallel generic events), the child selects the picture in each pair that best describes him/herself. Authors state the VECAT has good internal consistency and test–retest reliability.
Winzelberg AJ Eppstein D Eldredge KL Wilfley D Dasmahapatra R Dev P Barr-Taylor C, 2000	Eating Disorders	N = 60 (I = 31, C = 29) 8-week intervention and three-month follow up. Comparison of Web-based and classroom based psychoeducational interventions to reduce body dissatisfaction and eating disorders/behaviors/attitudes.	Behavior change	Longitudinal randomized study	IV = Web-based intervention, Class room intervention DV = Change in body satisfaction questionnaire scores, Eating disorder examination questionnaire, EDI-Drive for thinness scale	Evidence of feasibility for an Internet intervention to provide education via the Internet. At follow up, the intervention group showed improvement in body image and a decrease in the drive for thinness measures compared to controls.	Body satisfaction questionnaire (BSQ) has internal consistency of .97, test-retest validity =0.88, and concurrent validity coefficient = .66. EDI drive for thinness subscales have cronbach's alpha between .65 and .90.
Andersson G Stromgren T Strom L Lyttkens L, 2002	Tinnitus	N = 117 (I = 53, C = 64) Web-based cognitive behavioral therapy (CBT) to decrease distress caused by tinnitus.	Cognitive Behavioral Therapy	Longitudinal, randomized, Crossover design 6 month intervention, six month control	IV = Use of Web-based structured interview, treatment interactions, self-help program and weekly diaries DV = CBT Treatment efficacy evidenced by change in tinnitus reaction questionnaire, annoyance, anxiety sensitivity, depression scores	Reductions of tinnitus-related annoyance and anxious and depressive mood.	Tinnitus Reaction Questionnaire (TRQ) 26-item scale internal consistency of .96, test-retest correlation r=.88, Swedish version reported α = .97. Hospital anxiety and depression scales (HADS) show α=.82, α-.90 respectively.
Soetikno, RM. Mrad, R. Pao, V. Lenert, L., 1997	Ulcerative colitis (UC) and Quality of Life	N = 100 (I = 53, C = 47) Compared self-administered Internet based SF 36 and Irritable bowel QOL specific questionnaires (IBDQ) to paper-based administration.	Not discussed	Randomized Trial	IV = Use of Web-based assessment tool DV = Response demonstrating Validity of MOS 36 and IBD assessment surveys	Web-based scores on the IBPD tool were statistically different. Web participants had a wider range of scores and lower mean scores than clinic cases.	MOS-SF 36 Reliability cronbach's alpha: Phys. function .88-.93; Phys. role limits.84-.96; Pain .80-.90, social function .68-.85; Mental health .82-.95; Emot. role limits 80-.96;Vitality .85-.96;Gen.health .78-.95.

TABLE 2.3. SUMMARY OF REVIEWED STUDIES (CONTINUED)

Author and date	Intervention Focus	N and study characteristics	Conceptual framework	Design	Variables/Behavior Change Variable	Study Findings	Reliability of Effect Variable Instrument
Homer C, Susskind O, Alpert HR, Owusu M, Schneider L, Rappaport LA, Rubin DH, 2000	Asthma	N = 137, (I = 76,C = 61) children ages 3-12, 12-month study Effectiveness of interactive multimedia educational software program about asthma vs. control who reviewed printed educational materials with a research assistant.	Self efficacy theory	Longitudinal Randomized study	IV = Use of Interactive tool DV = Acute care use (ED, OP clinic), reports of asthma severity. Parent/child knowledge of asthma.	No differences were demonstrated between the 2 groups in primary or secondary outcome measures. Both groups showed improvement in all outcomes. Increased knowledge after use of the computer program. Children reported having enjoyed using the program.	Child Health Questionnaire (CHQ-PF50) assessed functional status. 11 multi-item scales covering the physical, emotional and social well-being of children. Internal consistency alphas of .39-.96 (mean.72)
Lange A, Rietdijk D, Hudcovicova M, van de Ven JP, Schrieken B, Emmelkamp PM, 2003	Posttraumatic Stress Disorder	N = 184 (I = 122, C = 62) 5-week study consisting of two, 45 minute writing session per week consisting of self confrontation, cognitive reappraisal, and social sharing.	Behavior change	Longitudinal Randomized study	IV = Use of Web-based intervention DV = Change in Impact of Event (IES) scale, symptom checklist-90 scale	On most subscales, more than 50% of the treated participants showed reliable change and clinically significant improvement, The highest percentage change was found for depression and avoidance.	The IES *(Dutch version by Kleber & Brom, 1986). Uses* a 5-point Likert scale on experiences for a given symptom during the past week. Cronbach's alpha .66 -.78 for the Avoidance subscale and .72 -.81 for the Intrusions subscale.
Strom L, Pettersson R, Andersson G, 2000	Recurrent Headache	N = 102 (I = 20, C = 25, dropout = 57) 6-week intervention of applied relaxation and problem solving to treat recurrent headaches while minimizing therapist contact.	Self-help	Longitudinal Randomized controlled study	IV = Use of the Web-based training program for headache relaxation techniques and headache problem solving DV = Headache index measure, # headaches, intensity, Beck's Depression Inventory, Headache Disability Inventory	"The Internet has the potential to serve as a complement in the treatment of recurrent headache." A significant reduction in the number of headaches for the treated participants.	No validity or reliability discussion.
Southard BH Southard DR Nuckolls J, 2003	2^0 prevention heart disease	N = 106 (I = 53, C = 53) 6-month study comparing an Internet based program (SI) for nurse case managers to provide support, monitoring and education to patients with CVD. Tailored interactive home based system. Use was once a week for 30 minutes.	Not discussed	Longitudinal Randomized case control pre post study	IV = Use of Heartlinks DV = physiologic measure change, Minutes of exercise; MEDFICTS fat score; Depression score; Costs of care	Fewer CV events occurred in intervention (SI) than in control. Increased weight loss in SI group to control. Depression scores increased in both groups Minutes of exercise increased	Dartmouth (COOP) QOL assessment 8 factors and health status change score Becks Depression Inventory 21 items, Internal consistencies from .73 to .95.

TABLE 2.3. SUMMARY OF REVIEWED STUDIES (CONTINUED)

Author and date	Intervention Focus	N and study characteristics	Conceptual Framework	Design	Variables/Behavior Change Variable	Study Findings	Reliability of Effect Variable Instrument
Bell DS, Kahn CE Jr, 1996	Validity and Reliability assessment of Web-based MOS SF 36.	N = 4876 Web versions, 2471 MOS study Compared MOS SF 36 validity and reliability data of paper based documentation to Web-based version.	Not discussed	Convenience sample	IV = Use of Web-based SF 36 DV = Completion and Results of QOL subscales	97% of users completed the survey in < 10 minutes. Older participants required more time to complete the survey. Web participants had overall worse QOL subscale values	Subscale scores range from 0.76 to 0.90, similar to those of the MOS paper based reliability values.
Flatley-Brennan P, 1998	HIV/AIDS	N = 57 (I = 37, C = 20) 25-week study demonstrating the use and effects of a specialized computer network among persons living with AIDS,	Rogers Diffusion of Innovation Theory	Longitudinal Randomized, Repeated measures study	IV = Home-based computer network use DV = Reduce social isolation improve confidence skills in decision-making no differential decline in health status among PLWA.	No significant difference between experimental and control groups Use of the system did reduce social isolation once participant's levels of depression were controlled and that decision-making confidence improved as a function of number of accesses	Decision making confidence used a modified Saunders and Courtney 15 item - 22-item scale. (α=.80). Social isolation used Lin's expressive social support scale (α=.88). Health status used 7 item Activities of Daily Living subscale (α=.76)
Wu AW, Yu-Isenberg K, McGrath M, Jacobson D, Gilchrist K, 2000	HIV/AIDS	N = 164 Touch-screen PC (n = 63,) Interview (n = 50), or self-administration (n = 51).	Not discussed	Randomized trial	IV = Use of touch screen in clinic kiosk PC to complete assessment tools DV = Reported measures from MOS-HIV, AIDS Clinical Trials Group (ACTG), Baseline Adherence and ACTG Symptom Distress	The reliability was noted to be comparable to face-to-face interview and self administration of the paper based tool.	Reliability of MOS_HIV α=0.69-0.94 for all subscales. Interclass correlations range between 0.54-0.88 for each subscale .
Bangsberg DR, Bronstone A, Hofmann R, 2002	HIV/AIDS	N = 110 Computer-assisted patient self report vs. provider estimate of HIV medication Adherence.	Not discussed	Convenience sample	IV = Use of Computer assisted, self-administered interviews (CASI) kiosk PC to complete survey tools. DV = Patient self report and provider medication adherence estimate, errors taking medication	54% of patients made at least one error in reporting their medication regimen. Providers tended to overestimate their patients' adherence and correctly classified only 24% of nonadherent patients at the 80% adherence level.	Validation of patient HIV medication self report done using the Aids Clinical trias Group's (ACTG) reasons for missing medications survey, viral load and CD4 lab values to assess detectable and non-detectable levels.

Intervention = I; Control = C; IV = Independent variable; DV = Dependent variable; PLWA = People living with AIDS;

TABLE 2.4. DEMOGRAPHIC CHARACTERISTICS OF THE CUMULATIVE STUDIES

Author	Total N*	Attrition % From Enrollment To Final Follow Up			Mean Age in years (Range)	Gender	
		Intervention	Control	Study Duration		Males	Females
Andersson et al.	117	13%	7%	6 weeks	47.8	62	55
Bangsberg et al.	110	NA	NA	NA	46	96	14
Bell & Kahn	4876	NA	NA	NA	38.2	2455	2421
Celio et al. [36]	76	12%	31%	26 weeks	19.6 (18-36)	0	76
Christensen et al.	3430	48% reported combined		self paced	35.5	1567	1863
Chou	359	NA	NA	NA	42.3	278	79
Clarke et al.	299	41% reported combined		32 weeks	43.7	73	226
Flatley-Brennan	57	20%	12%	26 weeks	33.2	53	4
Gustafson et al.	204	12%	8%	26 weeks	34.6	184	20
Harvey-Berino et al.	46	4% reported combined		37 weeks	46.3 (31-60)	9	37
Harvey-Berino et al.	101	18% reported combined		78 weeks	48.4	18	83
Homer et al.	137	25%	20%	40 weeks	7.4 (3-12)	95	42
Krishna et al.	228	53%	58%	52 weeks	Not Specified	148	80
Lange et al.	184	53%	48%	5 weeks	47.8	Not Specified	
Marshall et al. [46]	655	14%	19%	10 weeks	43	321	334
Oenema et al.	198	NA	NA	NA	44	75	123
Ritterband et al.	24	0%	0%	3 weeks	8.4	5	19
Soetikno et al.	100	NA	NA	NA	44.5 (midpoint) (35-54)	55	45
Southard et al.	106	4%	0%	52 weeks	62 (37-86)	80	26
Strom et al.	102	44% reported combined		6 weeks	36.7 (19-62)	33	69
Winzelberg et al.	60	23%	31%	20 weeks	20 (18-33)	0	60
Wu et al.	164	NA	NA	NA	41.5	120	44
Combined**	11,633	21%	21%		41.5	5,727	5,590

*Sample size (N) was derived from the number of cases newly enrolled into each study
NA=Non-longitudinal Study
** Combined average age excluded: (1) Homer, et al.;[43] Ritterband, et al.;[48] Krishna, et al.:[44] subjects were all children 17 years of age or less. (3) Soetikno, et al.,[33] only age range and midpoint were reported. Gender data were not reported by Lange, et al.[45]. Attrition rates were combined only for those specifying intervention/control.

TABLE 2.5. WEB SITE USAGE STATISTICS

Author	Focus/Intervention	Average Intervention Time/ site session (in minutes/person)	Web Site session logon average (/ person)/ study duration (weeks)
Andersson, et al.	Tinnitus	Not discussed	Not discussed
Bangsberg, et al.	Computer Assisted Self-Reported Medication Adherence	Not discussed	Not discussed
Bell and Kahn	Quality of life using the SF-36	**4.5 min/p**	**Not discussed**
Celio, et al.	Eating Disorders	Not discussed	Not discussed
Christensen, et al.	Depression and Anxiety Prevention in the General Public	**9.47 min/p**	**280 person/6 wks**
Chou	HIV Self Care Symptom Management - Medication Taking	Not discussed	Not discussed
Clarke, et al.	Depression	**Not discussed**	**2.6 person/32 wks**
Flatley-Brennan	Use of ComputerLink Networking in Persons with HIV	**12.5 min/p**	**188 person/26 wks**
Gustafson, et al.	CHESS - In Persons With HIV	**Not discussed**	**1008 person/36 wks**
Harvey-Berino, et al.	Weight Loss Maintenance	Not discussed	Not discussed
Harvey-Berino, et al.	Weight Loss Maintenance	Not discussed	Not discussed
Homer, et al.	Asthma Education Program	Not discussed	Not discussed
Krishna, et al.	Asthma Education Program use by children	Not discussed	Not discussed
Lange, et al.	Post Traumatic Stress Disorder	**45 min/p**	**10 person/5 wks**
Marshall, et al.	Physical Activity	Not discussed	Not discussed
Oenema, et al.	Tailored Nutrition Education	Not discussed	Not discussed
Ritterband, et al.	Encopresis	**Nor discussed**	**14 person/3 wks**
Soetikno, et al. [	Ulcerative Bowel Syndrome	Not discussed	Not discussed
Southard, et al.	Prevention of Secondary Cardiovascular Disease	**25 min/p**	**47 person/26 wks**
Strom, et al.	Headache Disability	Not discussed	Not discussed
Winzelberg, et al.	Eating Disorders	Not discussed	Not discussed
Wu, et al.	HIV Touch Screen MOS HIV Administration	Not discussed	Not discussed
Combined		**21.6 min/p**	

TABLE 3.1. INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria:

- Publication date: January 1996 to June, 2004.
- Use of a cognitive behavioral theoretical framework
- A Web-based intervention/maintenance study, intended to influence behavioral change and/or self-efficacy health outcomes of participants.
- Either randomized and controlled clinical trials or convenience samples
- Descriptive studies using a baseline and post study score(s)

Exclusion Criteria:

- Publication date: prior to January 1996
- Procedural methods citations (methods papers, non-implemented studies)
- Prospective non-implemented studies/citations
- Provider focused studies, no client/patient participation
- Web site access only studies
- Professional practice studies
- Telephone based interventions
- Remote monitoring studies
- Interventions incorporating synchronous video

TABLE 3.2. WEB-BASED COGNITIVE BEHAVIORAL INTERVENTIONS WITH NO SPECIFIED MODEL

Name, year	n Control n Intervention Attrition (%)	Intervention Focus Time Frame	Behavior Change Variable	Instruments	Analytical Method	Theoretical Criteria Met Y (1) / N (0)			
						1	2	3	4
Clarke et.al., 2002	155, 144 (41%)	Psycho-educational tutorial to reduce depression 32 weeks	CESD depression score	Center for Epidemiologic Studies – Depression (CES-D) scale	Effect size estimation	1	1	1	0
Harvey-Berino, 2002	Minimal in person support (41) Frequent in person support (41), Internet support (40)	Weight loss maintenance 78 weeks	Change in weight loss behavior skills; change in physical activity	Paffenberger physical activity questionnaire; block food frequency questionnaire	Repeated measures ANOVA	1	1	1	1
Krishna, et.al., 2003	107,121	Pediatric Asthma management 52 weeks	Children's asthma knowledge score	Pediatric asthma care knowledge scale Pediatric asthma caregiver's quality of life questionnaire	Cochrane, Mantel-Haenzel ratios	0	1	1	1
Jenny & Fai, 2001	48,48 (56%)	Cardiac rehabilitation patient education program 8 weeks	Exercise self efficacy	10 item physical exertion self efficacy scale	Repeated measures ANOVA	1	1	1	1
Gustafson et.al., 2001	148,147 (6%)	CHESS Breast Cancer in young women 20 weeks	Breast cancer information competence	5 item information competency scale Quality of lide dimensions	Linear regression	1	1	1	1
Gustafson et.al., 1999	97, 107 (9.8%)	CHESS HIV/AIDS 36 weeks	Participation in health care	Participation in health care, Quality of life dimensions	ANCOVA	1	1	1	1

CB Theoretical Criteria:
Four criteria: 1) provided tools to identify the cognitive problem; 2) provided educational materials; 3) provided application methods for use by the user; and 4) provided measures to assess self efficacy change or self management change at multiple time periods (if it was a longitudinal study).

TABLE 3.2. WEB-BASED COGNITIVE BEHAVIORAL INTERVENTIONS WITH NO SPECIFIED MODEL (CONT.)

Name, year	n Control n Intervention Attrition (%)	Intervention Focus Time Frame	Behavior Change Variable	Instruments	Analytical Method	Theoretical Criteria Met Y (1) / N (0)			
						1	2	3	4
Brown, et.al., 2003	51, 102 adolescent portion; 47, 22 parent portion	1.Student Bodies adolescent eating disorder prevention program 2. Parent intervention 8 weeks	Change in response to body shape questionnaire, Eating Disorder drive for thinness scale	Body shape questionnaire (BSQ), Eating distorder drive for thinness scale (EDI) scale	Effect size estimates	1	1	1	1
Long & Stevens, 2004	58, 63	Adolescent eating disorders 4 weeks	Self efficacy change scores for dietary knowledge	Health behavior questionnaire (HBS) scales on dietary self efficacy for fat and sodium, fruit /vegetable consumption self efficacy scale, Youth and adolescent food frequency questionnaire (YAQ)	ANOVA	1	1	1	1
Winzelberg, et.al., 2000	29, 31	Student Bodies - Eating disorders 8 weeks	Change in response to BSQ, EDI	Body shape questionnaire (BSQ), Eating distorder drive for thinness scale (EDI) scale,social support scale	ANCOVA	1	1	1	1
Celio et.al., 2000	24 waitlist/control 27 student bodies Internet, 25 body traps classroom	Student Bodies - Eating disorders 24 weeks	Change in response to BSQ, EDI	Body shape questionnaire (BSQ), Eating distorder drive for thinness scale (EDI) scale,social support scale	ANOVA	1	1	1	1
Winzelberg, et.al., 2003	30, 42	BOSOM BUDDIES Breast cancer support group 12 weeks	Change in PCL distress scale, pain level, Quality of Life dimensions, depression	Posttraumatic stress disorder checklist (PCL), perceived stress level, CESD scale	Effect size estimation	1	1	1	1

Four criteria: 1) provided tools to identify the cognitive problem; 2) provided educational materials; 3) provided application methods for use by the user; and 4) provided measures to assess self efficacy change or self management change at multiple time periods (if it was a longitudinal study).

TABLE 3.2. WEB-BASED COGNITIVE BEHAVIORAL INTERVENTIONS WITH NO SPECIFIED MODEL (CONT.)

Name, year	n Control n Intervention Attrition (%)	Intervention Focus Time Frame	Behavior Change Variable	Instruments	Analytical Method	Theoretical Criteria Met Y (1) / N (0)			
						1	2	3	4
Zabinski, et.al., 2004	30, 30	Chat room support Intervention for eating disorders 8 weeks	Change in Change in support scale, Eating disorders scale	Eating disorder examination questionnaire, Rosenberg self esteem scale, perceived social support scale, online social support scale	ANOVA, Effect size estimations	1	1	1	1
Christensen, et.,al., 2004	178 control, 166 depression information only, 178 CBT (21%)	MOODGYM Depression self management 6 weeks	Depression and CBT knowledge score change	Center for Epidemiologic Studies-Depression (CESD) scale, Automatic thoughts questionnaire	Effect size estimates	1	1	1	1
Andersson, et.al., 2002	64, 53 (28%)	Tinnitus 52 weeks	Change in TRQ, HADS depression and anxiety scores, ASI scores	Tinnitus reaction questionnaire, Hospital anxiety and depression scale, Anxiety sensitivity index (ASI)	ANOVA	1	1	1	1
Anderson et.al., 2001	148, 148 (45%)	Nutrition for a Lifetime System (NLS) Nutrition behavior 26 weeks	Nutrition self efficacy	NLS food beliefs survey	SEM	1	1	1	1
Tate, et.al., 2001	35, 36 (22%)	Weight loss program 26 weeks	Change in body weight	Paffenberger activity scale, Block Food frequency questionnaire	ANOVA	1	1	1	1
Carlbring, et.al., 2003	11, 11	Panic Disorder 24 weeks	Use of applied relaxation and CBT methods assessed change in self report scales	Body sensations questionnaire(BSQ), agoraphibic cognitions questionnaire (ACQ), quality of life inventory	Effect size estmation	1	1	1	1
Ritterband, et.al., 2003	12,12	U CAN POOP TOO Pediatric encopresis 3 weeks	Change in knowledge and toileting behavior	Encopresis knowledge questionnaire (EKQ), Virginia encopresis/ constipation apperception test (VECAT)	T tests, Mann Whitney	1	1	1	1

Four criteria: 1) provided tools to identify the cognitive problem; 2) provided educational materials; 3) provided application methods for use by the user; and 4) provided measures to assess self efficacy change or self management change at multiple time periods (if it was a longitudinal study).

TABLE 3.2. WEB-BASED COGNITIVE BEHAVIORAL INTERVENTIONS WITH NO SPECIFIED MODEL (CONT.)

Name, year	n Control n Intervention Attrition (%)	Intervention Focus Time Frame	Behavior Change Variable	Instruments	Analytical Method	Theoretical Criteria Met Y (1) / N (0)			
						1	2	3	4
Strom, et.al., 2000	N=102 Descriptive study (56%)	Headaches 6 weeks	Relaxation techniques for headache, headache frequency	Headache disability index	ANOVA	1	1	1	1
Lange, et.al., 2003	62, 122 (22%)	Post traumatic stress disorder 5 weeks	Change in IES scale and symptoms scale, SCL-90 scale	Impact Event Scale (IES), Somatoform dissociation scale (SDQ-5) Symptom SCL – 90 for anxiety, depression, somatization, sleeping problems subscales	ANOVA	1	1	1	1
Lenert, et.al., 2003	N=49, Descriptive study	Smoking cessation 4 week pilot	Reduce or quit smoking	Not discussed	Chi square Descriptive statistics	1	1	1	1
Homer, et.al., 2000	61, 76 (22%)	Self efficacy for asthma 52 weeks	Change in asthma knowledge	Acute care use (ED, OP clinic), reports of asthma severity. Parent/child knowledge of asthma.	Poisson regression	1	1	1	1
Southard & Southard, 2003	52, 53	HEARTLINKSecondary prevention for cardio vascular disease self monitoring 24 weeks	Weight loss Body mass index	Dartmouth COOP Quality of life scale, Duke activity status, Beck depression inventory, Canadian angina ordering system	ANCOVA	1	1	1	1
Buhrman, et.al., 2004	24, 22 (9%)	Chronic back pain 8 weeks	Change in MPI, PAIRS, CSQ	Multidimensional Pain inventory scale (MPI), pain impairment relationship scale (PAIRS), Coping strategies questionnaire (CSQ)	ANOVA	1	1	1	1

Four criteria: 1) provided tools to identify the cognitive problem; 2) provided educational materials; 3) provided application methods for use by the user; and 4) provided measures to assess self efficacy change or self management change at multiple time periods (if it was a longitudinal study).

TABLE 3.3. WEB-BASED INTERVENTIONS UTILIZING SPECIFIED MODELS

Name, year	Theory/ Model	n Control n Intervention Attrition (%)	Intervention Focus Time Frame	Behavior Change Variable	Instruments	Analytical Method	Theoretical Criteria Met Y (1) / N (0)				
							1	2	3	4	5
Bock et. al., 2001	TTM/SOC	(15%) 59, 61	Physical activity maintenance 52 weeks	Physical activity time/week	Physical activity participation; Perceived benefits/barriers to physical activity inventory; Process of change instrument	Repeated measures ANOVA	0	1	1	NA	NA
Marshall et. al., 2003	TTM/SOC	(22%) 328, 327	Physical activity Programs, 8 weeks	Active Living-mediated physical intervention	International Physical Activity Questionnaire (IPAQ) Short Past 7-day instrument.	ANCOVA	1	1	1	NA	NA
Escoffery et al., 2004	TTM/SOC	N=35 descriptive study	Smoking cessation, 26 weeks	Kick-IT! Smoking cessation	Not described	Descriptive statistics	1	1	0	NA	NA
Miller et.al., 2002	TTM/SOC	Paper based controls =88, web=83, web with interruption=84	Self assessment of alcohol use, 1 week	Validity testing for measures of alcohol self assessment	Stages of change readiness; Rating of alcohol use impact	Boot strapping sample analysis, correlations	1	1	0	NA	NA
Gullette & Turner, 2004	TTM/SOC	N=241 Descriptive study	Condom use in gay/bisexual men	Condom use	Stages of change ratings, self report condom use	Regression analysis	1	1	0	NA	NA
Wang & Etter, 2004	TTM/SOC	N=18,361 (80%) lost to follow up	Stop-Tabac smoking cessation, 3 -year study	Smoking cessation, change in smoking pattern	Stages of change rating, psychosocial variables	Descriptive statistics, z-scores	1	1	1	NA	NA
Nebel et. al., 2001	Self Regulation	N=126 Descriptive study	Diabetes education providing self care/self management skills	Carbohydrate content of various foods knowledge change	Measurement of carbohydrate content	ANOVA	1	1	0	0	1

TTM/SOC Criteria: 1)initial stage of the study participants; 2) outcomes by motivational stage; and 3) change in the study outcome by individual or group of individuals over time.
Self Regulation Criteria: 1) cause; 2) consequences; 3) identity; 4) timeline; 5) controllability (self efficacy)
Self Efficacy Criteria: 1) documentation of self belief ; 2) motivation for change; 3) affective change
Social Support Theory Criteria: 1) measures of existing peceived social support; 2) expected social support measures; 3) social support change measures; 4) Social support outcome effectiveness

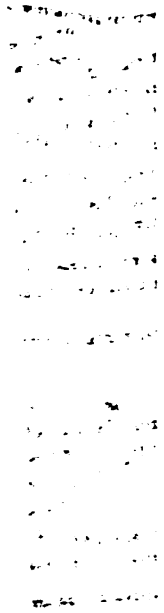


TABLE 3.3. WEB-BASED INTERVENTIONS UTILIZING SPECIFIED MODELS

Name, year	Theory/ Model	n Control n Intervention Attrition (%)	Intervention Focus Time Frame	Behavior Change Variable	Instruments	Analytical Method	Theoretical Criteria Met Y (1) / N (0)				
							1	2	3	4	5
Takabayashi et.al, 1999	Self Regulation	N=33, Descriptive study	Bronchial asthma 44 weeks	Asthma self management	Not described	Descriptive statistics	1	1	1	0	1
Clark, et.al., 1997	Self Regulation	115, 114 (5%)	Dietary management for hyperlipidemia, 12 weeks	CALS – Computer assisted learning system changes in total cholesterol	Cholesterol biomarker, cholesterohl/saturated fat index	Descriptive statistics	1	1	1	1	1
Barrera, et.al., 2002	Social Support Theory	40 control, 40 Social support, 40 Coach, 40 Social support with Coach	Type 2 diabetes use of support interventions 12 weeks	Perceived self support	Diabetes support scale, Interpersonal support evaluation list	ANCOVA effect sizes estimation	0	1	0	1	NA
Glasgow, et.al., 2003	Self Efficacy Theory	N=320 Control, tailored self management or peer support	Type 2 diabetes - 40 week maintenance program	Change in Kristal fat scale, Fat screen scale	Kristal Fat scale, 15 item fat screen scale Documentation of dietary goals	ANOVA	1	1	1	NA	NA
	Social Support Theory			Change in social support			0	0	0	1	NA
Chou, et.al., 2004	Orem's Self Care Deficit theory	237, 122 Descriptive study	HIV Self Care Symptom Management	HIV symptom management self care, taking prescription /OTC medications	Self care symptom management strategies manual; Sign and symptom checklist(rev).	ANOVA and Chi squared statistics	NA	NA	NA	NA	NA
Oenema, et.al., 2001	Weinstein's Precaution Adoption Process Model	102, 96 (2.5%) Descriptive study	Nutrition Education	Awareness of personal dietary intake levels	Food frequency questionnaire Intent to change diet	ANOVA	NA	NA	NA	NA	NA
Lorig et.al., 2002	Self efficacy Theory	296, 284 (45%)	Back pain 52 weeks	Self efficacy for back pain management	Six-item self efficacy instrument; Quality of life dimensions, health care utilization	Linear regression	1	1	1	NA	NA

TTM/SOC Criteria: 1)initial stage of the study participants; 2) outcomes by motivational stage; and 3) change in the study outcome by individual or group of individuals over time.
Self Regulation Criteria: 1) cause; 2) consequences; 3) identity; 4) timeline; 5) controllability (self efficacy)
Self Efficacy Criteria: 1) documentation of self belief ; 2) motivation for change; 3) affective change
Social Support Theory Criteria: 1) measures of existing peceived social support; 2) expected social support measures; 3) social support change measures; 4) social support outcome effectiveness

TABLE 4.1. DEMOGRAPHIC AND SYMPTOM CHARACTERISTICS N=240

Variables	**Mean**	**SD**	**Range**	
Age	41.83	7.60	22-68	
Years for Formal Education	11.57	2.53	0-19	
Years living with HIV	8.67	4.71	0 - 23	
Gender	Percent	Frequency		
Female	30.5%	74		
Male	65.4%	159		
Transgender	2.9%	7		
Ethnicity				
African American	72.4%	176		
White/Anglo	12.8%	31		
Hispanic/Latin	10.7%	26		
Native American Indian	1.2%	3		
Asian Pacific Islander	0.4%	1		
Other	1.2%	3		
Highest Education Qualification				
Grade School	23.9%	58		
High School	42.0%	102		
Technical/Vocational	12.3%	30		
College/Post-graduate	14.0%	34		
Other	7.8%	19		
Have an AIDS diagnosis Yes	51.4%	125		
Depression diagnosis at enrollment Yes	26.0%	64		
Variables	**Percentage**			
	Month 0	Month 1	Month 3	Month 6
Fatigue no	61%	66%	68%	64%
Fatigue yes	39%	34%	32%	36%
Muscle ache no	58%	66%	63%	54%
Muscle ache yes	42%	34%	37%	46%
Numbness feet/toes no	71%	78%	78%	80%
Numbness feet/toes yes	28%	21%	22%	20%
Symptom Intensity (range = 1 to 3) Mean (SD)				
Fatigue	1.8 (.79)	1.8 (.70)	1.7 (.73)	1.8 (.68)
Muscle ache	1.8 (.80)	1.8 (.76)	1.8 (.80)	2.0 (.70)
Numbness feet/toes	2.1 (.83)	2.0 (.83)`	1.8 (.71)	1.7 (.82)

TABLE 4.2 CORRELATIONS AMONG SYMPTOMS FOR EACH TIME PERIOD

	Baseline			Month 1			Month 3			Month 6		
	Fat	MA	Nb	Fat	MA	Nb	Fat	MA	Nb	Fat	MA	Nb
Fatigue	1			1			1			1		
MA	.54	1		.44	1		.60	1		.50	1	
Nb	.21	.27	1	.35	.28	1	.42	.34	1	.20	.21	1

Fat = Fatigue, MA = Muscle aches, Nb=Numbness of the feet/toes

TABLE 4.3 LAGGED EFFECT AND CONCURRENT SYMPTOM MODELS
LOG ODDS VALUES FOR SYMPTOM INTERCEPT AND CHANGE OVER TIME

Dependent variable = Fatigue		**Lagged Effect Models**		**Concurrent Models**	
Model Parameter	A.	B.	C.	D.	E.
fatigue outcome Intercept (OR)	.80	.30	.26	.18	.13
{logit}	{-0.218}	{-1.188}	{-1.336}	{1.738}	{-2.034}
(SE)	(0.194)	(0.300)	(0.358)	(0.709)	(0.369)
[z-score]	[-1.126]	[-3.964]	[3.731]	[2.923]	[5.518]
fatigue outcome Slope † (OR)	.97	1.0	1.0	.94	1.0
{logit}	{-0.037}	{0.046}	{0.008}	{-0.056}	{-0.042}
(SE)	(0.060)	(0.080)	(0.117)	(0.057)	(0.71)
[z-score]	[-0.619]	[0.576]	[0.068]	[-0.985]	[-0.585]
numbness (OR)		1.89	2.31	2.9	2.6
{logit}		{0..638}	{0.621}	{1.018}	{0.976}
(SE)		(0.278)	(0.276)	(0.279)	(0.276)
[z-score]		[2.298]	[2.250]	[3.644]	[3.544]
muscle ache (OR)		1.21	1.69	17.7	16
{logit}		{0.189}	{.247}	{2.877}	{2.832}
(SE)		(0.244)	(0.256)	(0.356)	(0.347)
[z-score]		[0.774]	[0.968]	[8.077]	[8.138]
Other diagnosis depression (I) (OR)			1.9		3.6
{logit}			{0.634}		{1.272}
(SE)			(0.512)		(0.407)
[z-score]			[1.238]		[3.119]
Other diagnosis depression (S) (OR)			1.0		.94
{logit}			{0.023}		{-0.056}
(SE)			(0.168)		(0.109)
[z-score]			[0.139]		[-0.519]
Covariance I with S (OR)	1.0	1.1	1.0	.82	.85
{logit}	{-0.020}	{-0.088}	{0.013}	{-0.197}	{-0.164}
(SE)	(0.200)	(0.371)	(0.117)	(.331)	(0.216)
[z-score]	[.102]	[-0.237]	[0.109]	[-0.867]	[-0.757]
Variance Parameters					
Slope (linear)					
{logit}	{0.012}	{0.075}	{0.070}	{0.061}	{0.053}
(SE)	(0.049)	(0.123)	(0.122)	(0.073)	(0.071)
[z-score]	[0.242]	[0.612]	[0.984]	[0.829]	[0.743]
Intercept					
{logit}	{3.680}	{2.64}	{2.181}	{3.113}	{2.579}
(SE)	(1.353)	(2.425)	(2.216)	(1.352)	(1.233)
[z-score]	[2.717]	[1.089]	[0.984]	[2.303]	[2.902]
Goodness of Fit					
Deviance	-1478.58	-1277.23	-1272.42	-1399.14	-1392.70
AIC	2985.14	2570.41	2570.83	2818.28	2809.40
BIC	3033.87	2614.89	2616.08	2853.40	2813.13

z score value $\geq$ 1.960, $p \leq 0.05$ † = quadratic, and cubic slopes fixed at 0.
Model 4.3.A. Fatigue only; Model 4.3.B. Fatigue, numbness, muscle ache; Model 4.3.C. Fatigue, numbness, muscle ache with "other diagnosis" of depression at baseline; Model 4.3.D. Fatigue, numbness, muscle ache; Model 4.3.E. Fatigue, numbness, muscle ache with "other diagnosis" of depression at baseline
To obtain the odds, use the inverse log function (log odds= 0.758, Inv odds = 2.13)
logit=log odds parameter estimate; OR=Odds ratio; SE=standard error; deviance=log likelihood; AIC=Aikike fit statistic, BIC=Bayesian fit statistic

FIGURE 2.1. SEARCH TERMS "WEB-BASED THERAPY" TRENDED BY YEAR OF PUBLICATION

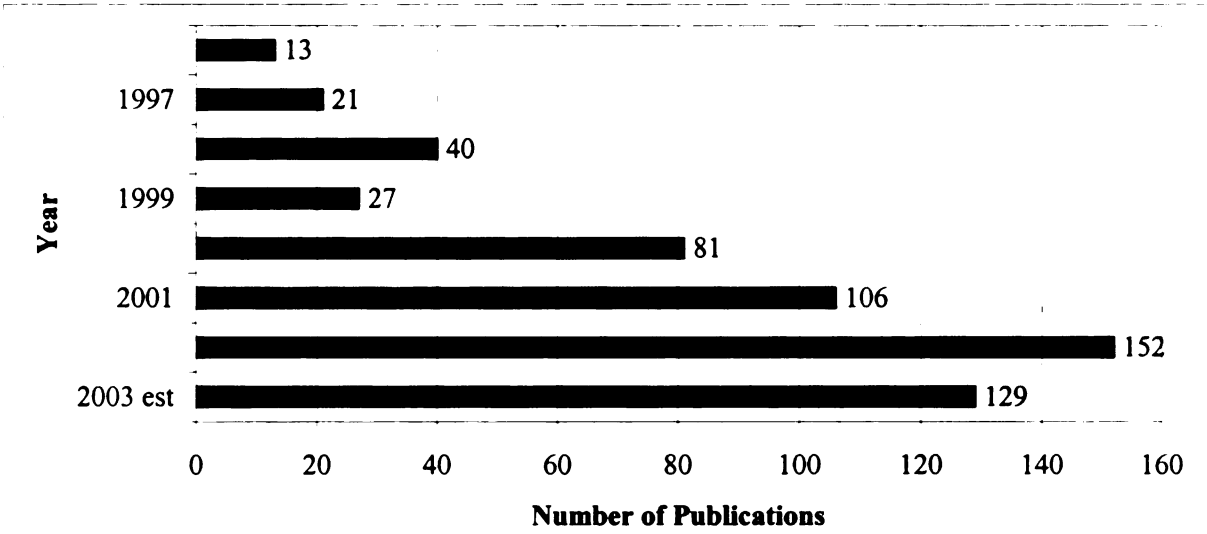


FIGURE 2.2. EFFECT SIZE (ES) FOR OUTCOME VARIABLES IN THE ANALYZED WEB-BASED INTERVENTIONS

Study #, Primary Author, Study Focus-Effect Variable	ES
1. Andersson, et al. Pre-post-follow up tinnitus reaction questionnaire	.16
2. Celio, et al. Change in Body Shape Questionnaire	.04
3. Christensen, et al. Goldberg Depression Scale-Mean Module 1 scores, gender combined	.07
4. Clarke, et al. Depression (CES-D) score change	.09
5. Flatley-Brennan, HIV Use of ComputerLink networking -Slower health decline	.25
6. Gustafson, et al. CHESS-HIV Change in participation in healthcare	.54
7. Harvey-Berino, et al. Weight Loss Maintenance – pounds lost	.15
8. Harvey-Berino, et al. 18-month weight loss maintenance	.64
9. Homer, et al. Change in knowledge of asthma-treatment	.57
10. Krishna, et al. Change in asthma knowledge scores in children	.40
11. Lange, et al. Change in impact of event intrusion and avoidance combined score	.75
12. Marshall, et al. Change in physical activity	-.01
13. Oenema, et al. Tailored Nutrition Education – Intention to change diet	.47
14. Ritterband, et al. Pediatric encopresis behavior change in bowel habit accidents	.57
15. Southard, et al. Minutes of exercise	.74
16. Strom, et al. Change in Headache Disability Inventory	.19
17. Winzelberg, et al. Reducing risk factors for eating disorders - change in body shape questionnaire scores	.03

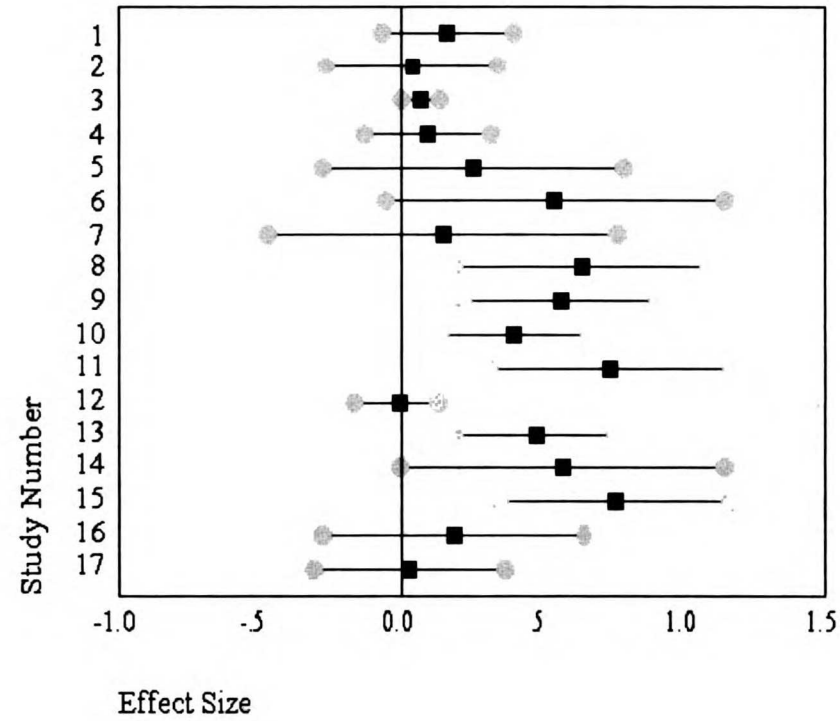


FIGURE 2.3. EFFECT SIZE (ES) EVALUATION OF STUDIES ASSESSING INSTRUMENTS/METHODS

Study #, Primary Author, Instrument	ES
1. Bangsberg, et al.– CASI Self Report HIV Medication Adherence	.44
2. Bell, et al. SF 36 QOL All Subscales	.29
3. Chou. HIV symptom self care –Taking medications, prescription, OTC medications	.16
4. Soetikno, et al. SF-36 QOL-All scales	-.23
5. Wu, et al. MOS-HIV QOL Survey-All scales	-.24

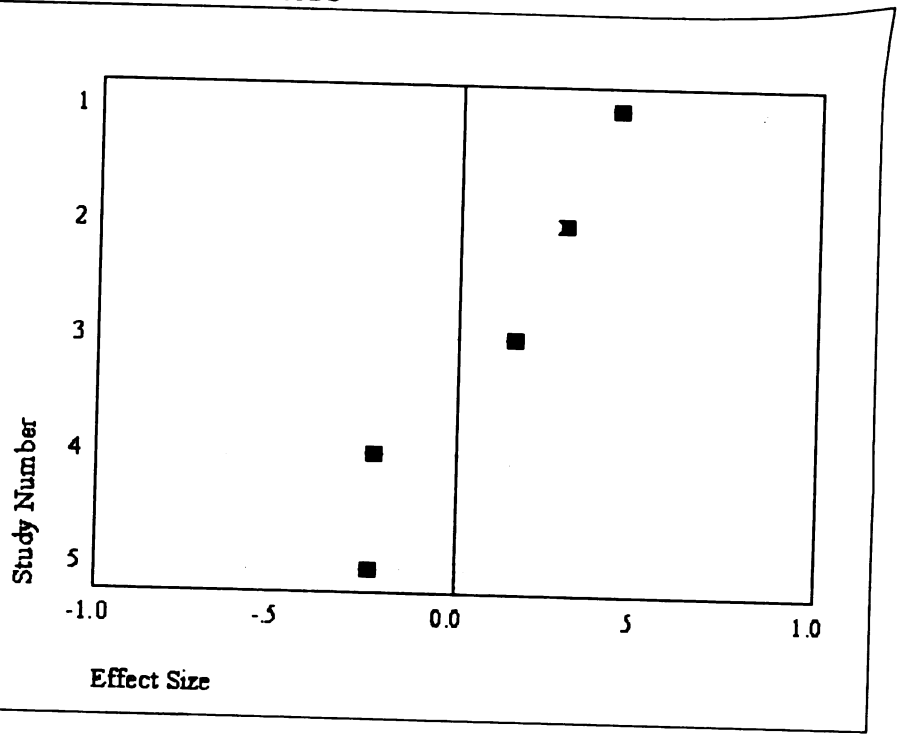
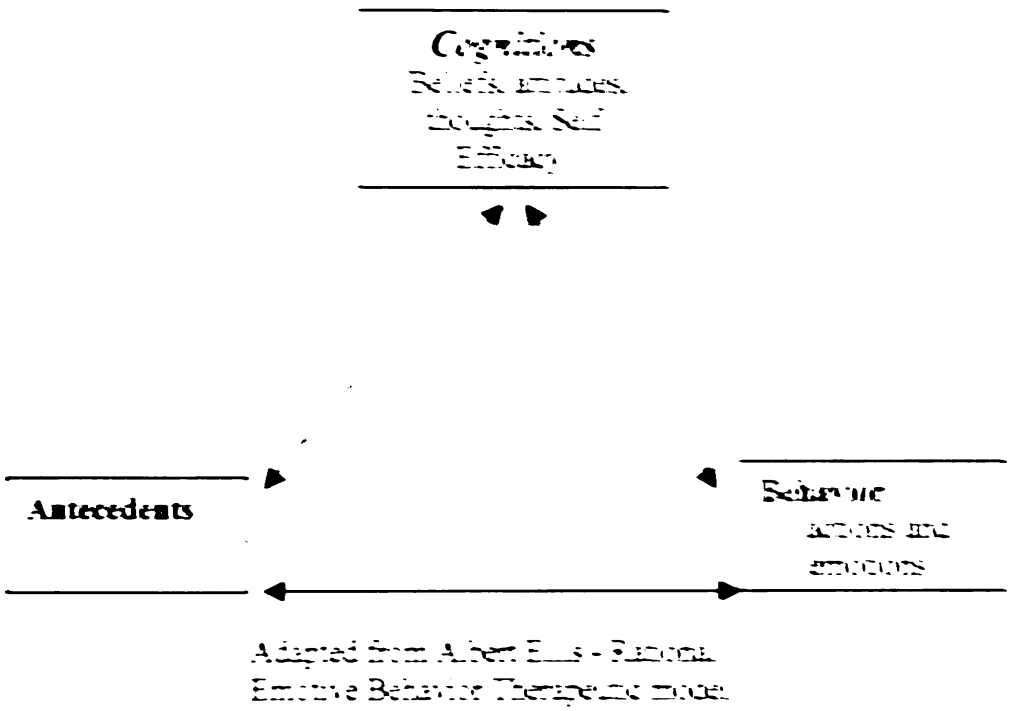
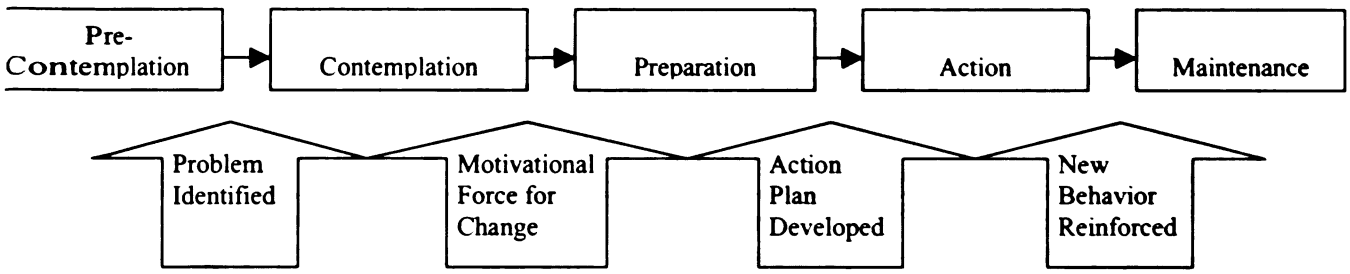


FIGURE 3.1 ANTECEDENT, BEHAVIOR, CONSEQUENCES (ABC) MODEL



Adapted from Albert Ellis - Rational Emotive Behavior Therapy (REBT) model

FIGURE 3.2. THE TRANSTHEORETICAL MODEL OF BEHAVIOR CHANGE (STAGES OF CHANGE MODEL)



The Transtheoretical Model of Behavior Change was developed by Dr. James Prochaska and his colleagues of the URI Cancer Prevention Research Center. Adapted from: Richard W. Scholl, University of Rhode Island, September 15, 2002. Used with permission.

FIGURE 3.3. THE SELF-REGULATION (COMMON SENSE) MODEL

from from Leventhal, Nerentz, & Steele, & Imm, 1984 (H. L. Leventhal, Nerenz, Steele, & Imm, 1984). Used with permission

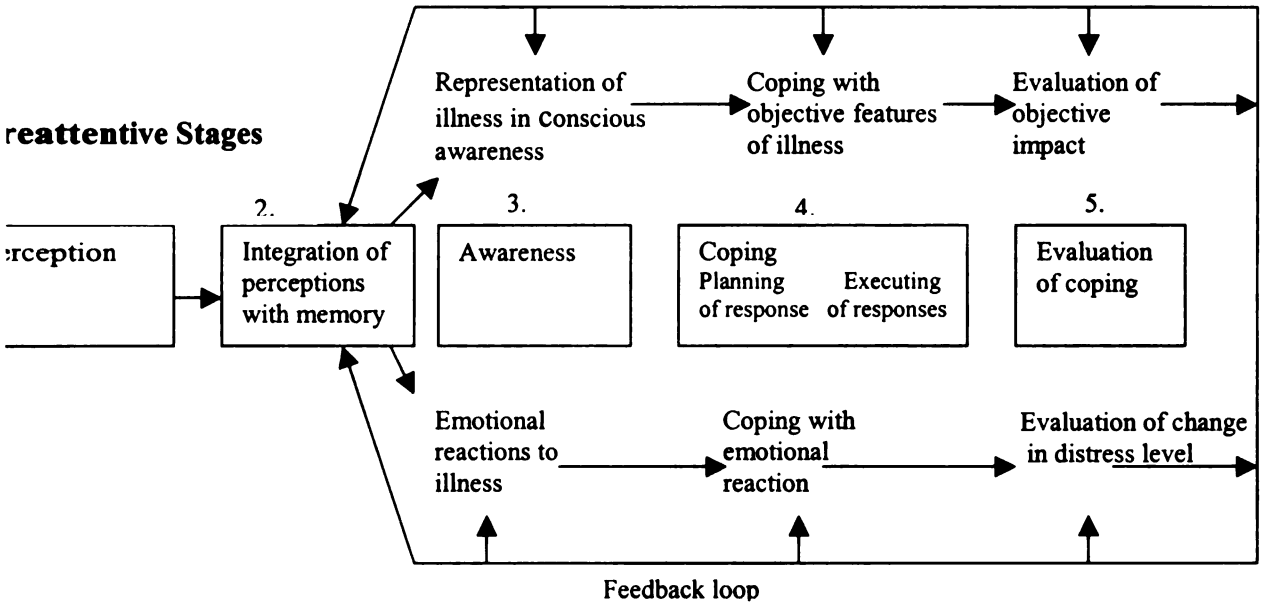
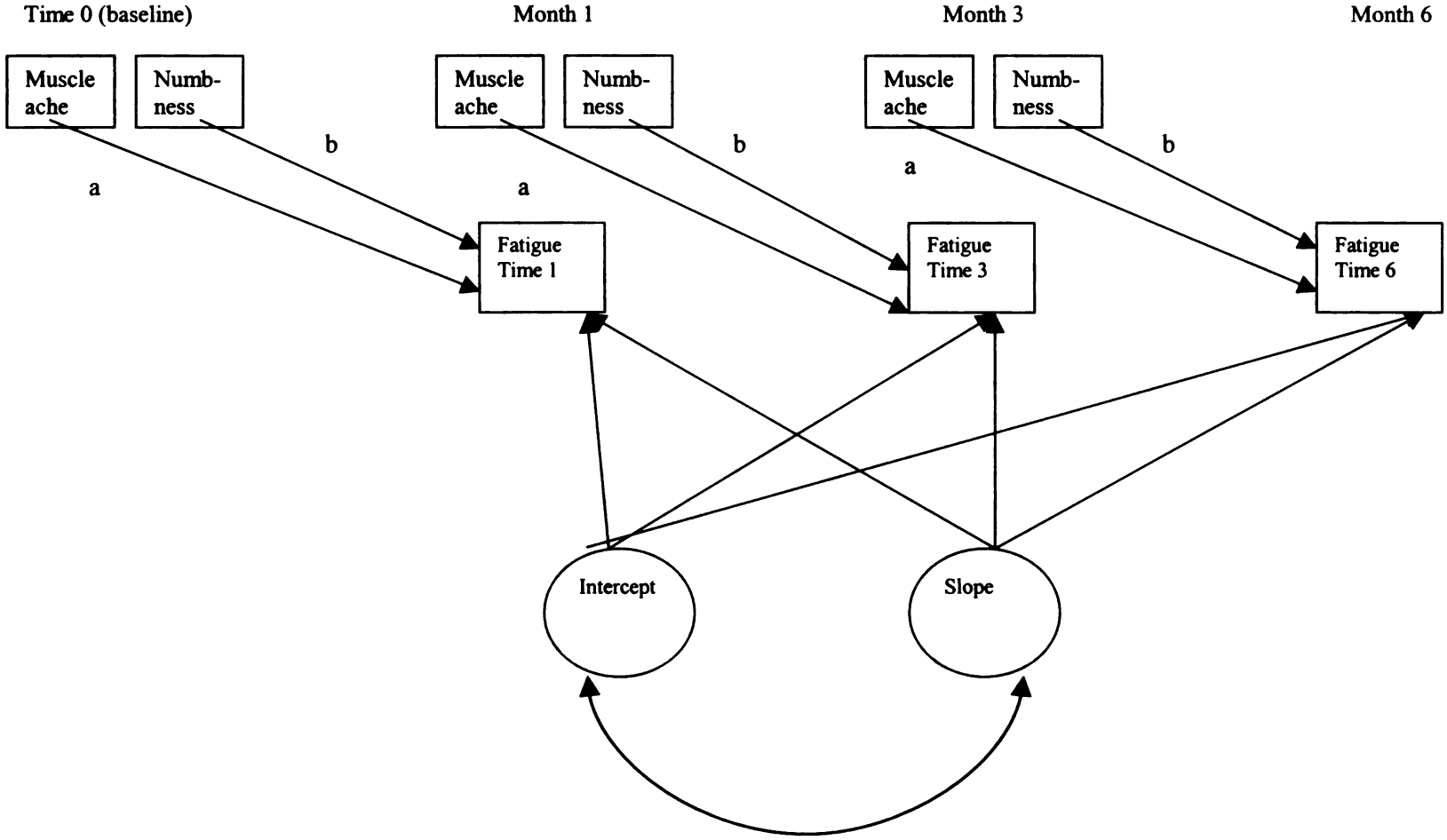


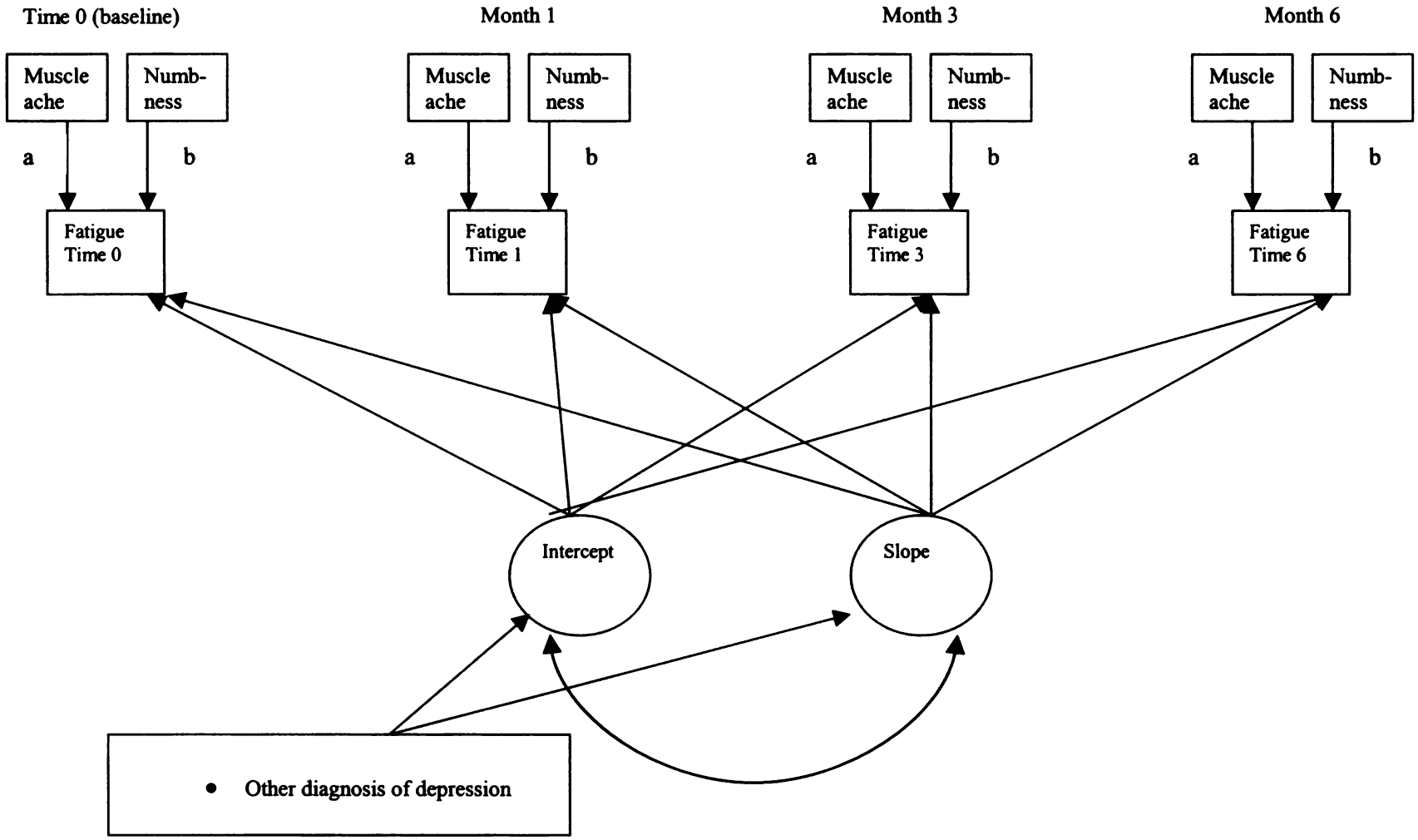
FIGURE 4.1. DIAGRAM OF THE SYMPTOM CHANGE LAGGED EFFECTS MODEL



a, b = constrained parameters
The same letter indicates that the parameters are constrained to be equal for each time period.

Time 0 = baseline; Time 1 = 1 month; Time 2 = 3 months; Time 3 = 6 months

FIGURE 4.2. DIAGRAM OF THE CONCURRENT SYMPTOM CHANGE MODEL



a, b = constrained parameters
The same letter indicates that the parameters are nstrained to be equal for each time period.

Time 0 = baseline; Time 1 = 1 month; Time 2 = 3 months; Time 3 = 6 months

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