Chapter 7

Efficacy, dose-response relationships and predictors of compliance in a web-based intervention aimed at empowerment of disability benefit claimants

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Abstract

Background.
Several issues can complicate the physician-patient encounter in medical disability assessment interviews. In an attempt to improve the physician-patient communication in this specific context, an online intervention was developed.

Objective.
To evaluate the efficacy, dose-response relationships, and to determine predictors of compliance of an online intervention, aimed at empowerment of disability claimants.

Methods.
We conducted secondary (per-protocol) analysis on data from a randomized controlled trial. In this trial, claimants applying for a work disability pension after being sick-listed for 104 weeks, were randomized into either an intervention group or control group. Participants who were randomized into the intervention group were able to logon to the website www.wiagesprek.nl. Participants from the control group were directed to a ‘sham’ website with commonly available information only. The primary outcome was empowerment. Secondary outcomes included coping, knowledge, claimant satisfaction, perceived justice, and physician satisfaction. Outcomes were assessed at baseline, two days before the disability assessment, as well as one day, 6 weeks, and 4 months after the disability assessment. To estimate efficacy, several sub-groups were analyzed on basis of four different compliance measures. Dose-response relationships were investigated by using total time registration data. Predictors of compliance were determined using a stepwise backward linear regression technique.

Results.
On basis of the per-protocol analysis it was found that the intervention did not have a significant positive effect on empowerment. However, knowledge, general self-efficacy, coping and active participation were significantly higher among high-compliant subgroups, compared to controls. The intervention had an adverse effect on claimants’ perceived procedural justice. Dose-response relationships were found for context-specific empowerment, knowledge, coping and claimants’ active participation. Being born in the Netherlands and feeling helpless towards the disability assessment predicted high compliance.

Conclusions.
Claimants who indeed used the intervention www.wiagesprek.nl prior to disability assessments had more knowledge and were more empowered before - and actively participating during - the disability assessment. However, no evidence was found on the benefits of this shift to the assessment in terms of satisfaction and perceived justice.
Introduction

For a decade, there has been a tremendous increase in the application of eHealth or web-based interventions in research. An important characteristic in the methodology of research that has been conducted in this field, is the fact that many participants in web-based trials fail to comply with the delivered intervention and discontinue using the application. This so-called “Law of Attrition” has serious consequences for the reported effectiveness of trials, in case these reports are based on intention-to-treat (ITT) analyses. In ITT analyses, all subjects included in the study, regardless of whether they actually comply with the intervention, are analysed. This means that if compliance with the intervention is low, the chances that this intervention demonstrates significant effects, declines. Undoubtedly, the question of main interest should always be whether a specific intervention is effective among all subjects included in the study (referred to as the “effectiveness” of an intervention). It can, however, be useful to understand the benefit of the intervention among a subgroup of those who did use it as intended (the so-called “efficacy” of an intervention). For this purpose, the most common analysis that is conducted as a supplement to ITT analyses is a per-protocol (PP) analysis.

To conduct adequate PP analyses, web-based research depends on an accurate assessment of program exposure or compliance. Unlike traditional interventions, Internet interventions allow for objective tracking and examination of compliance, and detailed information on usage of program components are therefore frequently available within a trial.

As such, in a recently conducted randomized controlled trial (RCT), in which an interactive website aimed at empowerment of disability benefit claimants was evaluated, extensive data was collected on website usage. This web-based intervention www.wiagesprek.nl was aimed at empowering claimants prior to a medical disability assessment with an insurance physician. Detailed information on the background and design of this trial have been described elsewhere. Results considering the effectiveness of this trial were disappointing, indicating no effects of the intervention on the primary outcome empowerment, and no beneficial effects on most secondary outcomes. Since compliance with the intervention was low in this study (only 52% of the intervention group used the intervention as intended), the lack of effectiveness may be caused by this feature. In this light, a more detailed evaluation between compliance and the outcomes that were measured in this study are necessary in order to get more insight into the exact working mechanisms of the intervention.

Therefore, in this study we aimed to investigate:

1) the efficacy of the intervention www.wiagesprek.nl by focussing on high-compliant subgroups.
2) the relationship between compliance (“dose”) and the outcomes measured (“response”).
3) which factors predicted high compliance in order to understand to which subgroup the intervention was appealing.

Methods

Design

A two-armed randomized controlled trial (RCT) was conducted among persons claiming a disability pension. A detailed description of the design of the study has been published elsewhere and will only be presented here briefly. The Medical Ethics Committee of the VU University Medical Center approved the study protocol (under number 08/194).

Participants

Participants were claimants for a disability pension according to the Dutch Work and Income Act (WIA). According to the WIA, this disability pension can be claimed after being sick-listed for 13 weeks. All disability claimants were recruited approximately 1-2 weeks prior to their appointment for disability assessment by an insurance physician. Recruitment took place through three different offices (Leiden, The Hague, Rotterdam) of the Dutch Workers Insurance Authority, UWV. UWV is the organization in the Netherlands responsible for evaluating disability claims. Together with a standard invitational letter and brochure from UWV, claimants received a study information brochure, which directed them to an online application form. This application form included questions concerning the study’s inclusion and exclusion criteria and an informed consent. Claimants were considered eligible to participate in the study if they had an email address. Recruitment took place over a 9-month period (January 2009 - September 2009).

All insurance physicians from the three participating UWV offices, and responsible for disability assessments concerning the Dutch Work and Income Act (WIA), were asked to participate in the study.

Randomization and blinding

Randomization took place at the individual claimant level. After baseline measurement, disability claimants were randomized into either the intervention or control group. Randomization to these two groups was done by block randomization. To prevent unequal groups, three blocks were created (three participating UWV offices). A computerized random number generator drew up an allocation schedule for each block. The use of a ‘sham’ website for participants of the control group (see below), caused claimants to be blinded for study design. Insurance physicians were aware of the study design, but were not informed about the group allocation of disability claimants.

Intervention group

Participants randomized in the intervention group were able to logon to the web-based intervention www.wiagesprek.nl with an obtained username and password. The development and exact content of this intervention has been described elsewhere. Briefly, the web-based intervention consisted of several components:

1) Five interactive modules (estimated walk through time: 120-150 minutes), in which claimants were prepared for their disability assessment step-by-step, based on an empowerment approach. This approach focused on increasing knowledge about Dutch disability legislation and disability benefit procedures, skill gaining (question asking, negotiating) to improve patient-physician communication, promoting active participation during the disability interview, increasing claimants’ awareness of their functional limitations with respect to work, and adapting expectations about disability assessment outcomes. Throughout the modules, subjects were asked to fill in short assignments, such as a knowledge quiz or, for example, an assignment aimed at taking along a personal health record to the interview.
2) General information and features concerning absenteeism from work (such as: social security law arrangements, disability assessment procedures, return to work opportunities, personal experiences of people who underwent disability assessment procedures, coping with disease and work disability, and links to other related websites).
3) A forum in which participants were able to interact with other claimants on issues such as coping with disease or experiences concerning disability assessments.
We measured coping strategy using the Dutch version of the Ways of Coping Questionnaire (WCQ, 12). Compliance was assessed by the so-called “session identifier approach” 7. User authentication (obtaining username and password at the beginning of every session) made it possible to register activity for each individual participant. With the appropriate scripting language (PHP: Hypertext Preprocessor) every activity on the website was registered in a MySQL database. This database contained weblogs with every row of the database containing the participants’ ID number, page number visited, time stamp (start and end time), and session number. To limit overestimation of activity time, a timer was built in the system, which stopped time registration when a participant was not active (scrolling, click or mouse movement) for a period of 8 minutes. With data from the weblogs it was possible to calculate the following variables for each participant: total time of intervention use, number of unique page views, and number of clicks. Calculating weblogs into user statistics was done using MATLAB version 7.3. Additionally, from a separate MySQL database, participant data on which modules were started and finished were distracted for each participant individually.

**Outcome measures**

Outcome measures were mainly extracted from online questionnaires. After baseline measurement (T0), participants were sent an email with a link to the questionnaires two days before their disability assessment (T1), as well as one day after their disability assessment (T2), 6 weeks (T3), and 4 months after their disability assessment (T4). Reminders were sent to decrease loss to follow-up. The following outcomes were assessed (and described elsewhere in more detail 15):

**Empowerment**

Empowerment was measured using the ‘VrijBaan’ questionnaire, an instrument designed to measure empowerment among people with a work disability 8. The VrijBaan questionnaire consists of 60 items divided over six subscales: Competence (13 items), Positive Identity (13 items), Avoidance (12 items), Group Orientation (9 items), Internal consistency of this questionnaire has shown to be good (all subscales had Cronbach’s alphas higher than 0.80). The subscales Competence and Impact were assessed at T0, T1, and T4. All other subscales were assessed at T0 and T4 only. In addition to the ‘VrijBaan’ questionnaire, mastery 9 and general self-efficacy 10, frequently mentioned as important components of empowerment 11, were assessed at T0, T1, and T4. Also, two questions of the VrijBaan questionnaire were re-formulated into the specific situation of the disability assessment, to measure context-specific empowerment.

**Coping strategy**

We measured coping strategy using the Dutch version of the Ways of Coping Questionnaire (WCQ, 13). Three dimensions of the WCQ were included: Problem Solving (8 items), Seeking Social Support (6 items), and Avoidance (7 items). Questions from these scales were adapted to the context of the disability assessment and were asked at T0 and T1. Scores were ranging from 1 to 4.

**Subjective knowledge**

With a 10-point Visual Analogue Scale (VAS), we measured claimants’ subjective knowledge about social security law arrangements and disability assessment procedures. At T0 we asked claimants: “How much do you know about social security law arrangements and disability assessment procedures?” (0= I know nothing, 10= I know everything). At T1 we asked: “To what extent did the intervention increase your knowledge about social security law arrangements and disability assessment procedures?” (0= my knowledge did not increase, 10= I gained maximum knowledge).

**Claimant satisfaction**

The satisfaction of claimants with their insurance physicians was measured (at T2) using the AStri questionnaire 13. This questionnaire has specially been designed to measure patient satisfaction in the field of insurance medicine. It contains 29 items, with a score ranging from 1 to 5.

**Claimant perceived justice**

To measure claimant perceived justice with the final verdict on their disability pension, a Dutch translation 14 of Moorman’s justice questionnaire 15 was used. This questionnaire consists of two subscales: distributive justice and procedural justice, both with a score ranging from 1 to 5. Perceived justice was measured at T3 only.

**Prognostic variables**

Prognostic variables that were used to determine predictors of compliance were: available preparation time (time between date of disability interview and date of enrolment), gender, age, country of birth, affinity with the Internet (range 1-4), level of education (high/medium/low), type of disease (musculoskeletal, mental, cardiovascular, other, or co-morbidity), work status (under contract or not), baseline knowledge on disability legislation (VAS-scale, range 0-10), perceived work ability (range 1-10), expectation of receiving a disability pension (yes/ partly/no), feeling helplessness towards the coming disability assessment (5-point Likert scale, ranging from 1= completely feeling helpless to 5= not feeling helpless at all), and feeling in control when thinking of the coming disability assessment (5-point Likert scale, ranging from 1= completely not in control to 5= totally in control).

Besides the questionnaires that were sent to claimants, insurance physician also received an email containing a link to a short questionnaire, directly after they assessed a claimant that participated in the study. Physician satisfaction with the disability assessment and claimants’ attitude were assessed using a questionnaire specially designed for this study. In this 10-item questionnaire physicians could react to specific statements on a 5-point Likert scale ranging from “I totally disagree” (1 point) to “I totally agree” (5 points). Additionally, physicians were asked to answer the question: “To what extent did the claimant had an active role in the disability assessment” on a 5-point Likert scale ranging from “very passive” (1 point) to “very active” (5 points). With this question we aimed to measure claimants’ active participation.

**Statistical Analyses**

**Baseline differences and attrition**

Baseline differences in demographic characteristics were investigated using Chi-square tests and independent sample t-tests. Drop-out attrition was defined as the phenomenon of losing participants to follow-up (e.g., participants who did not fill out follow-up questionnaires).

**Efficacy of the intervention**

A priori, effect modification and confounding were checked for gender, age, level of education, country of birth, disease type, internet use, work status, and perceived work ability for all outcome measures. Analyses to determine efficacy were then performed using multiple linear regression (continuous outcomes), with the follow-up outcome measure as the dependent variable. Assumptions of linear regression were verified. All analyses were adjusted for baseline values (if applicable) and possible confounding, thus creating an adjusted follow-up score 15. The parameters of interest were the regression coefficients (β), indicating the effect of the intervention compared to the control group. Efficacy was determined by defining the following
sub-groups: (1) a group of participants that finished all 5 modules (5MOD), (2) the most compliant quartile according to total time calculations (QUATIME), (3) the most compliant quartile according to number of clicks registered (QUACLICK), and (4) the most compliant quartile according to number of unique pages visited (QUAPAGE). In the PP-analyses these subgroups were compared to all participants from the control group. Previous reported ITT outcomes were displayed to compare these effectiveness measures with the four PP efficacy outcomes. In addition, effect modification and confounding were checked for the comparisons between the PP-subgroup based on total time calculations (QUATIME) and the control group. This was done to make sure a difference in effect between ITT analysis and QUATIME PP analysis was not caused by differences in baseline characteristics between these groups. All analyses were performed using SPSS version 15.0.

**Dose-response relationships**

To investigate the relationship between compliance and study outcome, efficacy was estimated for the following subgroups: participants from the intervention group that used the intervention for more than 1 hour, more than 2 hours, more than 3 hours, and more than 4 hours, respectively. These estimates (regression coefficients with their confidence intervals) were plotted in a graph to visualize the relationship between compliance and the outcome.

**Predictors of compliance**

To determine which prognostic factors were related to compliance, first, univariate multinominal linear regression analyses were performed to explore which of the prognostic factors (independent variables) were individually associated with compliance (dependent variable). In the second step, all the significant (P<0.1) factors from these univariate analyses were put in a multivariable model. Stepwise backward regression analyses were performed, resulting in a model with those prognostic factors that all were significant (P<.05) predictors of compliance.

**Results**

**Participants**

From the 2780 disability claimants who were approached, 242 (8.7%) were randomized into either the intervention group (n=123) or the control group (n=119). Baseline characteristics for participants are shown in Table 1. Despite adequate randomization procedures, gender was found to be unevenly distributed between the intervention and control group (x²=4.65, P=.03), and appeared to be a confounder. No other differences between the intervention and control group were found at baseline. In addition, Table 1 shows baseline characteristics of a subgroup of high-compliers (those with more than 3 hours of intervention use).

**Table 1. Baseline characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=123)</th>
<th>Control (n=119)</th>
<th>High-compliers (n=27)</th>
<th>P-value §</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>48.76 ± 10.0</td>
<td>48.55 ± 9.5</td>
<td>49.70 ± 8.5</td>
<td>P = .56</td>
</tr>
<tr>
<td>Female, %</td>
<td>53.7</td>
<td>67.2</td>
<td>48.1</td>
<td>P = .06</td>
</tr>
<tr>
<td>Country of Birth, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Netherlands</td>
<td>84.6</td>
<td>89.1</td>
<td>96.3</td>
<td>P = .25</td>
</tr>
<tr>
<td>Education, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>30.9</td>
<td>21.8</td>
<td>22.2</td>
<td></td>
</tr>
<tr>
<td>Middle</td>
<td>44.7</td>
<td>51.3</td>
<td>55.6</td>
<td></td>
</tr>
<tr>
<td>Higher</td>
<td>24.4</td>
<td>26.9</td>
<td>22.2</td>
<td></td>
</tr>
<tr>
<td>Internet use, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1 day/week</td>
<td>11.4</td>
<td>7.6</td>
<td>3.7</td>
<td>P = .56</td>
</tr>
<tr>
<td>1-2 days/week</td>
<td>17.1</td>
<td>19.3</td>
<td>11.1</td>
<td>P = .57</td>
</tr>
<tr>
<td>3-5 days/week</td>
<td>34.1</td>
<td>33.6</td>
<td>44.4</td>
<td>P = .88</td>
</tr>
<tr>
<td>&gt;5 days/week</td>
<td>37.4</td>
<td>39.4</td>
<td>40.7</td>
<td></td>
</tr>
<tr>
<td>Disease, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>20.3</td>
<td>29.4</td>
<td>25.9</td>
<td></td>
</tr>
<tr>
<td>Mental diseases</td>
<td>17.9</td>
<td>19.3</td>
<td>14.8</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>6.5</td>
<td>3.4</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>22.8</td>
<td>24.4</td>
<td>22.2</td>
<td></td>
</tr>
<tr>
<td>Co-morbidity</td>
<td>32.5</td>
<td>23.5</td>
<td>37.0</td>
<td>P = .59</td>
</tr>
<tr>
<td>Under contract with employer?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>65.0</td>
<td>63.0</td>
<td>59.3</td>
<td>P = .72</td>
</tr>
<tr>
<td>- Hours/week (if yes)</td>
<td>30.6 ± 9.5</td>
<td>29.2 ± 9.0</td>
<td>32.3 ± 7.8</td>
<td>P = .24</td>
</tr>
<tr>
<td>- Years in contract (if yes)</td>
<td>14.1 ± 10.7</td>
<td>14.9 ± 9.5</td>
<td>11.4 ± 9.0</td>
<td>P = .25</td>
</tr>
</tbody>
</table>

* Values are mean ± SD unless otherwise indicated.
§ P-value for the difference between high-compliers and the control group.
Drop-out attrition

Drop-out attrition rates were comparable for both study groups (no statistically significant differences at all follow-up measurements) and satisfactory for T2, T3, and T4 (20% or less). Drop-out attrition appeared not to be associated with compliance.

Compliance

During the time of the trial the intervention www.wagesprek.nl was accessed 329 times by the 123 participants of the intervention group. The average time these participants spent on the website was 115.3 minutes (SD 160), with an average of 2.7 sessions (SD 4.1). On average, 32.6 of the 91 unique pages (SD 11) were viewed; and 9.5 clicks (SD 11) were made. Among all participants from the control group, 45 (37%) never logged on after enrollment.

Efficacy of the intervention

Table 2 shows the results of the PP analysis, compared to the original ITT analysis. Although for most outcomes no significant changes were seen compared to the ITT analysis, some PP analysis showed that General Self-efficacy was significantly higher in the intervention group, whereas no effects were found with the ITT analysis, becoming stronger in the PP analyses. Efficacy measures of claimant satisfaction and perceived justice were comparable with the ITT analyses, indicating that more intense use of the intervention group never logged on to the intervention after enrollment.

Table 2. Efficacy of the intervention

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Intention-to-treat (ITT)†</th>
<th>Per-Protocol (SMOD) §</th>
<th>Per-Protocol (QUATIME)§</th>
<th>Per-Protocol (QUACLICK)§</th>
<th>Per-Protocol (QUAPAGE)§</th>
</tr>
</thead>
<tbody>
<tr>
<td>Empowerment [1-5]</td>
<td>Beta [95% CI]</td>
<td>Beta [95% CI]</td>
<td>Beta [95% CI]</td>
<td>Beta [95% CI]</td>
<td>Beta [95% CI]</td>
</tr>
<tr>
<td>Competence</td>
<td>0.02 (-0.06 to 0.09)</td>
<td>0.05 (-0.08 to 0.19)</td>
<td>0.06 (-0.06 to 0.17)</td>
<td>0.05 (-0.07 to 0.17)</td>
<td>0.10 (-0.02 to 0.21)</td>
</tr>
<tr>
<td>Impact</td>
<td>-0.09 (-0.21 to 0.03)</td>
<td>-0.12 (-0.24 to 0.01)</td>
<td>-0.08 (-0.26 to 0.10)</td>
<td>-0.03 (-0.22 to 0.16)</td>
<td>-0.12 (-0.31 to 0.07)</td>
</tr>
<tr>
<td>Context-specific</td>
<td>0.03 (-0.16 to 0.22)</td>
<td>0.09 (-0.23 to 0.40)</td>
<td>0.09 (-0.26 to 0.09)</td>
<td>0.16 (-0.15 to 0.47)</td>
<td>0.13 (-0.16 to 0.42)</td>
</tr>
<tr>
<td>General Self-efficacy [1-5]</td>
<td>0.03 (-0.07 to 0.12)</td>
<td>0.07 (-0.29 to 0.15)</td>
<td>0.09 (-0.29 to 0.10)</td>
<td>0.05 (-0.25 to 0.14)</td>
<td>0.14 (-0.01 to 0.29)*</td>
</tr>
<tr>
<td>Mastery [1-5]</td>
<td>-0.10 (-0.23 to 0.02)</td>
<td>-0.07 (-0.29 to 0.15)</td>
<td>-0.09 (-0.29 to 0.10)</td>
<td>-0.05 (-0.25 to 0.14)</td>
<td>-0.13 (-0.32 to 0.07)</td>
</tr>
<tr>
<td>Coping [1-5]</td>
<td>0.07 (-0.07 to 0.18)</td>
<td>0.14 (-0.06 to 0.33)</td>
<td>0.22 (0.05 to 0.39)*</td>
<td>0.16 (-0.02 to 0.33)*</td>
<td>0.22 (0.05 to 0.39)*</td>
</tr>
<tr>
<td>Problem Solving</td>
<td>0.09 (-0.10 to 0.01)</td>
<td>0.04 (-0.19 to 0.23)</td>
<td>0.05 (-0.16 to 0.26)</td>
<td>0.05 (-0.18 to 0.31)</td>
<td>0.10 (-0.08 to 0.31)</td>
</tr>
<tr>
<td>Social Support</td>
<td>-0.01 (-0.10 to 0.08)</td>
<td>-0.04 (-0.18 to 0.05)</td>
<td>-0.04 (0.14 to 0.20)</td>
<td>-0.03 (-0.19 to 0.14)</td>
<td>-0.02 (-0.18 to 0.14)</td>
</tr>
<tr>
<td>Avoidance</td>
<td>0.00 (-0.11 to 0.10)</td>
<td>0.00 (-0.18 to 0.11)</td>
<td>0.00 (-0.24 to 0.10)</td>
<td>0.00 (-0.30 to 0.26)</td>
<td>0.00 (-0.31 to 0.23)</td>
</tr>
<tr>
<td>Knowledge [0-10]</td>
<td>1.38 (0.59 to 2.17)*</td>
<td>2.97 (1.65 to 4.30)*</td>
<td>3.14 (1.99 to 4.29)*</td>
<td>2.93 (1.22 to 3.64)*</td>
<td>2.58 (1.38 to 3.78)*</td>
</tr>
<tr>
<td>Claimant Satisfaction [1-5]</td>
<td>-0.10 (-0.28 to 0.08)</td>
<td>-0.14 (-0.43 to 0.14)</td>
<td>-0.10 (-0.38 to 0.18)</td>
<td>-0.02 (-0.30 to 0.26)</td>
<td>-0.04 (-0.31 to 0.23)</td>
</tr>
<tr>
<td>Perceived Justice [1-7]</td>
<td>-0.17 (-0.62 to 0.31)</td>
<td>-0.06 (-0.55 to 0.44)</td>
<td>-0.34 (-0.83 to 0.16)</td>
<td>-0.36 (-0.85 to 0.14)</td>
<td>-0.16 (-0.66 to 0.34)</td>
</tr>
<tr>
<td>Distributive</td>
<td>-0.24 (-0.32 to 0.05)</td>
<td>-0.06 (-0.55 to 0.44)</td>
<td>-0.34 (-0.83 to 0.16)</td>
<td>-0.36 (-0.85 to 0.14)</td>
<td>-0.16 (-0.66 to 0.34)</td>
</tr>
<tr>
<td>Procedural</td>
<td>-0.50 (-0.94 to 0.04)</td>
<td>-0.16 (-0.71 to 0.36)</td>
<td>-0.36 (-0.83 to 0.16)</td>
<td>-0.36 (-0.85 to 0.14)</td>
<td>-0.16 (-0.66 to 0.34)</td>
</tr>
<tr>
<td>Physician Satisfaction</td>
<td>-0.01 (-0.16 to 0.15)</td>
<td>-0.16 (-0.71 to 0.36)</td>
<td>-0.36 (-0.83 to 0.16)</td>
<td>-0.36 (-0.85 to 0.14)</td>
<td>-0.16 (-0.66 to 0.34)</td>
</tr>
<tr>
<td>Duration meeting [min]</td>
<td>-0.65 (-5.21 to 3.90)</td>
<td>-0.79 (-7.95 to 6.37)</td>
<td>-0.36 (-0.83 to 0.16)</td>
<td>-0.36 (-0.85 to 0.14)</td>
<td>-0.16 (-0.66 to 0.34)</td>
</tr>
<tr>
<td>Claimants’ active participation [1-5]</td>
<td>0.14 (-0.10 to 0.40)</td>
<td>0.07 (-0.28 to 0.43)</td>
<td>0.41 (0.09 to 0.73)*</td>
<td>0.23 (-0.10 to 0.57)</td>
<td>0.31 (-0.04 to 0.66)*</td>
</tr>
</tbody>
</table>

† a higher value is indicating a less desirable score
* significant at P<.050
** significant at P<.010
† 123 participants from the intervention group included in the analysis
§ 31 participants from the intervention group included in the analysis
¶ 27 participants from the intervention group included in the analysis
Differences between the four methods of defining high-compliant subgroup existed. As an example, comparing a high compliant subgroup on basis of total number of mouse clicks with the control group showed a significantly positive effect of the intervention on general self-efficacy, while at the same time this was not the case if a high compliant subgroup was defined on basis of total time on the website. Moreover, outcomes of the PP analysis based on the amount of modules finished (5MOD), somewhat differed from the other PP analyses.

**Dose-response relationships**

Figure 1 displays dose-response relationships between compliance (all participants (ITT), participants using the intervention for more than 1 hour (>1 HR), 2 hours (>2 HR), 3 hours (>3 HR), and 4 hours (>4 HR), respectively, and some outcomes measured in the study. Only outcomes for which dose-response relationship were seen, are displayed in Figure 1. For the remaining outcomes, no changes in the estimated intervention effect were found when compliance with the intervention increased. The 21 participants from the intervention group who spent more than 4 hours on the website, showed a significant increase of 10% (Mean difference [MD] = 0.40, 95% confidence interval [CI] 0.06 to 0.73) in context-specific empowerment, compared to the control group. Furthermore, coping (subscale problem solving) and claimants active participation was significantly higher among high compliant claimants from the intervention group than control group participants, and this effect became stronger in subgroups that were increasingly compliant. The intervention was effective in increasing claimants knowledge about social security law arrangements and disability assessment procedures. These effects gradually became stronger when analyzing subgroups of claimants that spend increasing time with the intervention. On all other outcomes (claimants' satisfaction, perceived justice, physician satisfaction and the duration of the meeting) no beneficial effects of the intervention were found. A significantly adverse effect of the intervention on procedural justice was found, but this effect did not change with increasing compliance.

**Predictors of compliance**

Univariate multinominal linear regression analyses revealed two independent prognostic variables that were associated with compliance. These were country of birth, and feelings of helplessness towards the disability assessment. Both factors remained to be significantly associated with compliance, when put in the multivariate model. This implicates that Dutch-born claimants were more compliant with the intervention (P=.044) compared to non Dutch-born claimants, and claimants feeling more helpless towards their disability assessment ended up using the intervention more intense (P=.037).
Discussion

This study aimed to investigate the efficacy of the intervention www.wiagesprek.nl: a web-based intervention aimed at empowerment of disability claimants, prior to a disability assessment by an insurance physician. Furthermore, we aimed to investigate the relationship between compliance (‘dose’) and the outcomes measured in the study (‘response’), and to explore what claimant factors were predicting high compliance with the intervention.

Main Findings

The intervention www.wiagesprek.nl was not efficacious on the study’s primary outcome empowerment, measured using the ‘VrijBaan’ questionnaire. However, a clear dose-response relation of compliance with the intervention was found on context-specific empowerment. With increasing compliance rates, the effects of the intervention on context-specific empowerment gradually became stronger. Dose-response relationships were furthermore detected for the outcomes claimants’ active participation, coping (subscale avoidance), and knowledge. Finally, two significant predictors of compliance were found. These were: nationality (Dutch-born claimants used the intervention more than non-Dutch-born claimants) and feeling helpless towards the disability assessment (claimants feeling more helpless before the assessment were more compliant with the intervention).

Interpretation of Findings

Empowerment

The main research question of this study (does the intervention enhances claimant empowerment?) can be answered ambiguously. On the one hand, from the results on the main (‘VrijBaan’) questionnaire used in this study, it can be concluded that using the intervention was not related to any increase in levels of empowerment. On the other hand, however, intervention use did have an effect on context-specific empowerment, measured with adapted items from the ‘VrijBaan’ questionnaire. A possible reason for this difference can be the fact that the intervention did empower claimants (on the short term) towards the disability assessment, but this was not rigorous enough to improve a more general sense of empowerment. In this light, general empowerment might be less responsive to situation-specific changes, that may have occurred as a consequence of the intervention, since the instrument by which it was being assessed contained items that measure relatively stable personal characteristics (for example: “I have little control over things that happen to me”, VrijBaan questionnaire, subscale Impact). Context-specific empowerment, on the contrary, was assessed by questions that might be more responsive to changes in the context of the disability assessment (for example: “I have little control over my upcoming disability assessment”). This difference in questionnaires might possibly explain the results of this study on the outcome empowerment. The positive effects of intervention use that were found on (short-term) context-specific empowerment can be underlined by the positive effects we found of intervention use on context-specific coping and the finding that claimants who used the intervention were more actively participating in the meeting with the insurance physician. With regard to coping, it was found that compliant participants were more actively preparing themselves for the disability assessment, by, for example, trying to understand the content of the assessment or thinking of ways on how to deal with the assessment. Moreover, physicians experienced participants who used the intervention thoroughly to have a more active role during the disability assessment than those who did not. Altogether, it seems plausible to conclude that claimants who used the intervention adequately were somewhat “activated” or “empowered” during the disability assessment, but that this change was only related to the disability assessment itself and did not contribute to a more stable and long-term change in empowerment.

As to the practical relevance of the found effects it is difficult to conclude what the importance of these improvements might be. However, in terms of relative improvements, we can conclude that there is no evidence that empowering disability claimants prior to disability assessment enhances satisfaction (both claimant and physician), claimant perceived justice, or duration of the interview. Therefore, for insurance medicine practice, no benefits of empowering claimants prior to disability assessment can be expected.

Efficacy versus Effectiveness

This study aimed to investigate the efficacy of the intervention www.wiagesprek.nl. With focusing on efficacy, we have tried to answer the question of whether the intervention works under ideal circumstances, in this case, under the condition that the intervention really was used. In real life, as we know from previously conducted studies, the intervention www.wiagesprek.nl will most likely suffer from a high rate of non-usage. In our RCT, it was found that 33% of the claimants who were randomized into the intervention group did not use the intervention at all, and only about 32% used the intervention as intended. The consequences of these findings are that the described results are only applicable to a subgroup of intervention users. Estimates are that, of the roughly 38,000 workers in the Netherlands who annually claim disability, only 1200 (3%) will use the intervention as intended. Therefore, the results of this study are only applicable to this low proportion of claimants.

Strengths and Limitations

Blinding of patients and physicians in this trial were unique in the area of web-based research. We used a ‘sham’ website, with commonly available information only, to serve as a control condition. Through the use of this parallel used website, claimants were not aware of the study design and the existence of two separate study conditions. Moreover, physicians were not told which claimant was randomized into what group, and thus, were blinded for the allocation of the claimant who they assessed for disability. Although the response rate at the T1 measurement (66%) was disappointing, internal validity was strengthened by the drop-out attrition rate of 18% at 14-month follow-up. Furthermore, we used an accurate method to assess compliance with the intervention. As it is increasingly being stimulated and recommended to measure and report compliance in web-based research 2,3, in this trial, the so-called ‘session identifier approach’ made it possible to register web activity for each participant individually and thereby gave a reliable estimation of individual program exposure. This method of determining compliance is much more reliable than, for example, using self-reported program exposure data or simply registering if a certain component of an intervention was used or not. In addition, we introduced a timer, which stopped individual time registration from the moment a participant was not actively using (scrolling, clicking or mouse movement) the website for a period of 8 minutes. This built-in timer minimalized possible overestimation of program exposure through eliminating the contribution of ‘passive’ time registration. The availability of other compliance measures than total time registration, such as unique page views and total number of modules finished, made it possible to compare different methods of compliance measures and thereby determine the consequences of the selection of different measures on the study’s outcomes.

There are also limitations of our study to consider. The first is that external validity of the efficacy outcomes is low. As frequently is the case in web-based research, non-usage attrition was high in this study. All results presented in this study, however, describe the effects of the intervention under the condition that it was used properly. Automatically, this means that if the intervention would be implemented in daily practice, the effects on a whole population can differ from the ones reported in this study. Second, our decision for choosing certain compliance measures is rather arbitrary. As compliance is only a proxy measure for actual
exposure to the intervention, the choice for using the most compliant quartile for the efficacy outcomes, and time registration for determining dose-response relationships, can be subject to discussion. Finally, the PP analyses conducted in this study can be subject to bias. Per-protocol analysis implicitly rest on the assumption that the groups of participants that are compared (high compliant intervention participants versus the complete control group) are equivalent. Because there is a selection of high-compliant intervention group participants, this selection may have led to the fact that participants from two groups that were compared had different characteristics. In our analysis, however, we thoroughly checked for confounding. Although some baseline characteristics were found to be unevenly distributed between high-compliant subgroups and the control group (see Table 1), adjusting for these variables in our analysis did not change the estimate of the effect. Thus, this would make it more plausible that the effects we found were a true effect of the intervention, rather than being caused by the two groups not being equivalent.

**General Implications for Web-based research**

This study shows that the so-called “sessions identifier approach” is a feasible method from which compliance data can easily be distracted and used for subgroup PP analysis. Although many compliance measures can be chosen in order to determine high-compliant subgroups for the PP analysis, to our opinion, total time registration combined with a timer to distract “passive time” is the most comprehensive way to examine efficacy of an intervention. Many other measures might be subject to bias, which is the case with defining compliance as the total number of modules finished, number of unique pages viewed, or number of mouse clicks. These measures can be biased by, for example, participants who quickly go through different elements or modules of the web application, without absorbing or interacting with the content.

Time registration is not biased by this feature. Although much more robust, total time registration can overestimate actual compliance in cases a participant glancing at the screen will be equally registered as a participant actively reading content. A built-in timer which stops time registration if a participant is not active (mouse clicking, scrolling) for 8 minutes can take away part of this bias and contribute to a more accurate assessment. The timer that was included in this study stopped time registration after 8 minutes of non-activity, but no evidence exists today on which time period is the best to use. Finally, an advantage of total time registration is that it makes the determination of dose-response relationships possible, which is demonstrated in the present study. When examining dose-response relationships, additional insight can be gained on how much time spent on the intervention is at least needed for the application to be effective on certain outcomes. In general, as a complement to ‘standard’ ITT analysis, all these factors can contribute to a better understanding of an intervention and its exact working mechanisms. Since Internet interventions allow for objective tracking and examination of program use, not including these measures and analysis in the evaluation of intervention, seems a missed opportunity.

**Conclusions**

From the results of this efficacy study it can be expected that, when implemented in daily insurance medicine practice, claimants who will use the intervention www.wiagesprek.nl prior to disability assessment will have more knowledge on Dutch social security law arrangements and disability assessment procedures. Claimants will also be activated and empowered towards the disability assessment, but this shift will not have any consequences on a more general sense of empowerment and satisfaction with the assessment. Furthermore, perceived procedural justice can be expected to be lower among claimants who use the intervention. Moreover, insurance physicians will not be more satisfied with empowered claimants compared to non-empowered claimants and the duration of the disability assessment will not change as a consequence of a more empowered claimant. When considering implementation, policy makers should take into account the low uptake of the intervention. Due to this low uptake the intervention will have a low impact on a population level.
Reference List

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