Promoting work participation of non-permanent workers with psychological problems: An evidence-based approach to occupational health care
Audhoe, Selwin

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Is the “Brainwork Intervention” effective in reducing sick leave for non-permanent workers with psychological problems? Results of a controlled clinical trial

Selwin S Audhoe
Karen Nieuwenhuijisen
Jan L Hoving
Bonne JH Zijlstra
Monique HW Frings-Dresen
Judith K Sluiter

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ABSTRACT

Purpose
Unemployed, temporary agency and expired fixed-term contract workers having psychological problems are a particularly vulnerable group, at risk for sickness absence and prolonged work disability. A return-to-work (RTW) intervention called “Brainwork” was developed. The aim of this study was to assess the effectiveness of the ‘Brainwork Intervention’ (BWI) in reducing the duration of sick leave compared to usual care (UC) over a six-month follow-up.

Methods
In a controlled clinical trial, we compared BWI (n = 164) to UC (n = 156). The primary outcome was duration of sick leave. Secondary outcomes were duration of sick leave starting from Social Security Agency transfer, number of hours of paid employment during the follow-up period, degree of worker participation, level of psychological complaints and self-efficacy for RTW. Protocol adherence (BWI) was considered sufficient when at least three of the five protocol steps were followed. Cox regressions, linear and ordinal regression, and Mixed Model analyses were performed.

Results
The BWI resulted in a non-significant reduction of the duration of sick leave compared to UC (171 days versus 185 days; HR = 1.34; 95% CI 0.91–1.97; \( p = 0.14 \)). For those working (26%) during the six-month follow-up, the mean number of hours of paid employment was significant higher in the UC group (443 hours versus 257 hours; \( p = 0.005 \)). No significant differences were found for other secondary outcomes. Protocol adherence was 10%.

Conclusions
The BWI as performed did not result in a significant reduction of the duration of sick leave compared to UC.

Trial registration
The Netherlands Trial Register (NTR); NTR4190.
INTRODUCTION

Psychological problems are highly prevalent in the general and working populations [1-4]. Sickness absence due to psychological problems such as depression, anxiety and stress-related disorders is increasing in many high-income countries, contributing substantially to disability benefits and permanent exclusion from the labor market [5-8]. Only 50% of the workers sick-listed for six months or more due to psychological problems return to work (RTW) [8].

Among the working population, unemployed and temporary agency workers and workers with expired fixed-term contracts are at even greater risk for sickness absence and prolonged work disability due to psychological problems [9-12]. These workers who are without a permanent employment contract, also known as non-permanent workers, represent a particularly vulnerable group within the working population. In the Netherlands, non-permanent workers have a three times greater risk of becoming long-term work disabled (>18 months) compared to workers with a permanent employment contract (employed workers) [13]. Compared to sick-listed employed workers, sick-listed non-permanent workers perceive their health status more negatively and encounter more psychosocial barriers (such as personal problems, debts, addiction, legal proceedings, care issues) for their RTW [10,11,14,15]. Moreover, these workers experience a greater distance to the labor market compared to sick-listed employed workers as there is no workplace to return to when sick-listed [14].

In recent years, relatively more workers have become non-permanent workers, due, in part, to the worldwide economic crisis and changing labor market conditions [10,16-18]. To illustrate the increase in non-permanent workers in the Netherlands, in 2013 more than a quarter of the active labor force was working on a temporary basis, compared to almost 18 percent in 2001 [19]. Considering the growing rate of non-permanent workers, the increasing rate of sick leave due to psychological problems and the higher risk for prolonged work disability in this group, it is surprising that the development of effective RTW interventions for non-permanent workers is lagging behind [20]. As a result, there is a growing need to develop RTW interventions for these workers that address the absence.
of a workplace to which they can return. Focusing on the ability to work is important since working even a few hours during the RTW process is a strong predictor for successful RTW [21].

In the Netherlands, the sickness absence counseling of non-permanent workers is conducted by a team of occupational health (OH) professionals from the Dutch Social Security Agency (SSA). The team of OH professionals consists of an insurance physician (IP), vocational rehabilitation counselor, labor expert, nurse practitioner and secretary. The current sickness absence counseling of non-permanent workers (usual care) is not structured according to a fixed protocol. Furthermore, there is no protocol for the referral to RTW programs. Professionals of the SSA developed the Brainwork Intervention for non-permanent workers who are sick-listed due to psychological problems. The Brainwork Intervention uses an activating approach, which means that in the early stage of sick leave (within two to five weeks), the workers are encouraged to engage in physical exercise and undertake activities aimed at regaining control and functional recovery while job coaches actively support their search for jobs (temporary or otherwise). The content of the intervention varies and is tailored to the severity of the psychological problems and functional impairments, as well as to the specific psychosocial problems encountered by the sick-listed worker. The interventions were given by OH professionals in collaboration with external partners (e.g., vocational rehabilitation agencies and mental health institutions/professionals) specialized in addressing the target group. It is expected that this approach will lead to functional recovery and reduce the sick-leave duration of the sick-listed worker.

The main aim of this study was to assess the effectiveness of the Brainwork Intervention in reducing the duration of sick leave for non-permanent workers with psychological problems compared to usual care. A secondary aim was to assess the effectiveness of the Brainwork Intervention on the: (1) duration of sick leave starting from SSA transfer; (2) degree of worker participation; (3) number of hours of paid employment during follow-up; (4) level of psychological complaints; and (5) self-efficacy for RTW.
METHODS

Study design and setting
The present multicenter study is a two-armed quasi-randomized controlled clinical trial (CCT) with a follow-up period of six months. This study was carried out in collaboration with three regional offices of the SSA across the Netherlands (east, south-west, south regions). Participants were allocated to two groups: an intervention group that received the Brainwork Intervention and a control group that received usual care. The design and procedures of the study have been described in detail in an earlier publication of the study protocol [22].

Study population
Between January 2014 and September 2014, all newly received sick reports of non-permanent workers from the participating SSA offices who met the inclusion criteria were included in the study until the required number of at least 300 participants was reached. The inclusion criteria were: (1) being an unemployed or temporary agency worker or worker with an expired fixed-term contract; (2) age between 18 and 64 years; (3) being sick-listed and not expected to RTW within two weeks after either reporting sick or having contact with the vocational rehabilitation counselor of the SSA. (An RTW expectation within two weeks of reporting sick corresponds to Brainwork category classification 0; see Table 1 in Chapter 6); (4) having psychological problems/complaints as the main reason for a sickness benefit claim; and (5) having adequate command of the Dutch language. The exclusion criteria were: (1) recent pregnancy or up to three months after delivery; (2) substance addiction (alcohol, drugs or medicines) as the main reason for a sickness benefit claim; (3) having a severe psychiatric disorder with an expected recovery of more than one year, e.g., hospitalization or day treatment. (This corresponds to Brainwork category classification 3; see Table 1 in Chapter 6).

In the regular work process of the SSA, each sick-listed worker (i.e., intervention and control group) receives a segmentation code by the nurse practitioner or IP within two weeks after the SSA received the sick report. The code indicates the professionals’ estimated duration for sick leave based on a self-report SSA-specific questionnaire. The questionnaire includes, among other things, topics about
health complaints, the tasks the worker cannot perform due to the complaints, RTW expectancy of the worker, information about medical treatment and whether the worker performs volunteer work. Four segmentation codes can be distinguished: code 1 indicates a sick-leave duration of less than 13 weeks; code 2 a sick-leave duration of between 13 and 52 weeks; code 3 a sick-leave duration of between 52 and 104 weeks; and code 4 indicates no expectancy of recovery or work participation. For our study, segmentation codes 1 and 2 were relevant. These codes correspond to the Brainwork category classification 1 (estimated recovery <3 months) and 2 (estimated recovery 3 to 12 months). See Table 1 in Chapter 6 for an overview of the Brainwork category classification of the worker.

The power analysis obtained using the nQuery Advisor program showed that 144 participants were needed per group (288 total) to detect a mean difference in duration of sick leave of 40 days [22].

The Medical Ethics Committee of the Academic Medical Center in Amsterdam (AMC), University of Amsterdam approved the study design. The study was listed in the Netherlands Trial Register (NTR) under NTR4190.

**Procedure**

**Participants**

After inclusion in the study, the workers received a letter from the staff IP of the appropriate regional SSA office, on behalf of the investigators. The purpose of this letter was to provide information about the study and to ask for the worker’s cooperation (informed consent) in completing questionnaires during the study. At follow-up, only the sick-listed workers who signed an informed consent to fill the questionnaires were approached for follow-up questionnaires.

**Occupational health professionals**

At each SSA office, an existing team of OH professionals was designated as an intervention team and one as a control group team. Instruction and coaching sessions were given to all of the OH professionals on the intervention team. Furthermore, team members received a two-day training course in motivational interviewing. The training provided the OH professionals with the motivational
interviewing skills necessary to activate the sick-listed workers’ participation in the Brainwork Intervention, to initiate positive behavioral changes and to address sick-listed workers’ resistance to change.

**Interventions**

**Brainwork Intervention**

The rationale of the Brainwork Intervention, the Brainwork category classification of the worker and an overview of the Brainwork Interventions per category have been described in detail elsewhere [22], see Table 1 and Figure 1 in Chapter 6. Briefly, the Brainwork Intervention is designed to assist non-permanent workers who are sick-listed due to psychological problems with their RTW. Within five working days of the SSA receiving the sick report, a face-to-face contact takes place between the OH professional and the sick-listed worker. The customized content of the intervention varies depending on the severity of the psychological problems and the specific psychosocial problems the sick-listed worker needs to address. The components of the intervention can include an exercise program, vocational training, gym membership, and attention tailored to their mental and/or psychosocial problems (e.g., dealing with coping problems or eye movement desensitization and reprocessing (EMDR) for persons with impaired trauma counseling). All interventions are combined with counseling by vocational rehabilitation agencies with the aim of achieving reintegration into primary paid work or enhancing work experience. Based on the category classification, explicit goals and timetables for recovery were formulated [22].

**Usual care**

The control group received counseling according to care as usual in the SSA setting. Usual care consisted of minimal involvement on the part of the IP (one or two patient contacts in a year) and slightly more intensive contact with other OH professionals. In this scenario, the active sickness absence counseling starts at a later point in time during the sick-leave process, which in practice can range from a few weeks to six months after reporting sick. An SSA file search in 2008 showed that it took an average of 10 weeks before the first contact of the sick-listed worker with the IP occurred [23]. Furthermore, it was found that a late start (≥8 weeks) of the sickness absence counseling, a late first IP assessment (≥10 weeks)
and fewer IP assessments (<1 contact in 12 weeks) during the sick-leave period were associated with a longer duration of sick leave. Due to the absence of a protocol for referral to RTW programs, the use of RTW interventions remains limited in usual care. In contrast to the Brainwork Intervention group, in usual care, early reintegration into primary paid work or enhancing work experience is not an explicit goal. The main tasks of the IP in usual care are to evaluate the sickness benefit claim of the sick-listed worker and the workers’ fitness for work, while the main tasks of other OH professionals are to monitor the sick-listed worker, e.g., to check if the worker is complying with the rules of the sickness benefit act by seeking medical treatment for his complaints and if the symptoms of the worker are improving. The interventions received by the workers in the usual care group were registered.

**Outcome measures**

**Data collection**

Data regarding sickness benefit duration, paid employment during follow-up and degree of participation are continuously registered by the SSA and were routinely collected from the computerized SSA database. We used data from a follow-up period of six months after the date on which the SSA received the sick report. Data regarding psychological complaints and self-efficacy for RTW were collected from self-reported questionnaires at baseline and four months after the SSA received the sick report. Data entry of the self-reported data was performed by a research assistant using a unique code for each participant.

**Primary outcome**

The primary outcome measure was duration of sick leave and operationalized as duration of the sickness benefit period (in calendar days) from the first day of reporting sick until the termination of the sickness benefit. The sickness benefit ends after a full RTW (e.g., for temporary agency workers) or if the participant is declared fit for work by the IP (e.g., for unemployed workers).

**Secondary outcomes**

The secondary outcome measures available at this time point were duration of sick leave starting from SSA transfer, number of hours of paid employment during
follow-up, degree of participation, psychological complaints and self-efficacy for RTW. The duration of sick leave starting from SSA transfer is operationalized as the actual duration (in calendar days) that the sick-listed worker was under counseling by the regional office of the SSA until the termination of the sickness benefit. The degree of participation was coded in the ordered categories of: no participation, non-paid work (volunteer work or working in a work experience situation) and paid work, consecutively.

Psychological complaints were measured using the Dutch translation of the General Health Questionnaire-12 (GHQ-12) [24]. The GHQ-12 is one of the most common mental health tools in use and a well-established screening instrument designed to detect non-psychotic psychiatric disorders in people in community and medical settings. It is a 12-item self-report questionnaire concerning the respondent’s assessment of his or her present mental health state. Each item is rated on a four-point response scale. Using the scoring method (0-1-2-3), the sum score ranges from 0 to 36. Low scores reflect better mental health. ‘Self-efficacy for RTW’ was measured using a validated 11-item RTW self-efficacy questionnaire, with response categories on a 6-point scale [25]. Participants were asked to respond to statements about their jobs, imagining that they would start working their full contract hours again the following day (in their present emotional state/state of mind). In a pilot study of workers on sick leave due to common mental disorders, this questionnaire had a satisfactory construct validity and good reliability [25]. A mean score across the 11 items was used to compute the scale score. The scale score ranges from 1 to 6. Higher scores reflect higher self-efficacy levels.

**Randomization and blinding**

Within each of the three participating regional offices of the SSA participants were allocated to the Brainwork Intervention team or usual care team using quasi-randomization. The allocation procedure has been described in detail elsewhere [22]. To ensure equal distribution of the different types of workers in the intervention team and usual care team, the sick-listed workers were pre-stratified based on the type of worker (i.e., unemployed and temporary versus expired fixed-term contracts). Equal distribution of the types of workers in
both teams was important as the starting point of the intervention was different for the subgroups of workers. The person who allocated the worker to either teams was unaware of the type or severity of the psychological problem, or of any other characteristics of the participants.

The participants, OH professionals and intervention partners such as vocational rehabilitation agencies and mental health institutions/professionals were not blinded to the allocation result.

**Protocol adherence**

The following five protocol steps were used as process measures for adherence to the protocol: (1) telephone contact by the OH professional with the worker within two days of the SSA receiving the sick report; (2) face-to-face contact between the vocational rehabilitation counselor and the worker within five working days of the SSA receiving the sick report; (3) bilateral consultations between the vocational rehabilitation counselor and IP within two days after the face-to-face contact with the worker; (4) consultation of the IP, within one to two weeks of the bilateral consultations; (5) timely start of the intervention within eight working days after consultation of the IP.

The adherence to the protocol was considered sufficient when three of the five protocol steps were followed within the given time frame and with the start of the intervention being timely in all cases.

**Statistical analyses**

All statistical analyses were conducted at workers’ level according to the intention-to-treat principle. To determine whether the quasi-randomization was performed successfully, descriptive statistics were used to compare the baseline measurements of both groups. If necessary, the main analyses were adjusted for prognostic dissimilarities. For those five aspects (process measures) of the protocol which were fixed for all participants, the protocol deviations were analyzed as preparation for the per-protocol analyses. The intention was to compare the results of the intention-to-treat analyses with the per-protocol analyses to assess the presence of bias due to protocol deviations.
Cox regressions analyses were performed to determine hazard ratios between the intervention and control group for the primary outcome duration of sick leave and the secondary outcome duration of sick leave starting from SSA transfer. The cases for whom the sickness benefit had not been terminated at six months follow-up were censored for the Cox regressions analyses. Ordinal logistic regression analysis was performed to determine the odds ratio for degree of participation between the intervention and control group. For those working during the six-month follow-up period, the number of hours of paid employment during follow-up between the intervention and control group were compared with a linear regression model. Linear Mixed Models were used for the secondary outcomes psychological complaints and self-efficacy for RTW, with random parameters for individual baselines and fixed parameters for differential growth between the intervention and control group. Results in all analyses were adjusted for regional SSA office and type of worker (unemployed and temporary agency worker versus expired fixed-term contract worker). All analyses were performed using IBM SPSS Statistics version 22.0. In all analyses, \( p \)-values at or below 0.05 (two-tailed) were considered to be statistically significant.

RESULTS

Recruitment of participants

During the recruitment period (January 2014 to September 2014), 485 potentially eligible participants were screened. Of these, 320 participants were included in the study. The Brainwork Intervention team counseled 164 participants and the usual care team 156 participants. Reasons for excluding the potentially eligible participants were: (1) expected recovery within two weeks of reporting sick or having contact with the vocational rehabilitation counselor of the SSA; (2) having a severe psychiatric disorder with an expected recovery later than one year; (3) psychological problems/complaints were not the main reason for a sickness benefit claim; (4) no adequate command of the Dutch language; (5) (recent) pregnancy; (6) substance addiction; (7) sickness claim not accepted by the SSA; and (8) not belonging to one of the three participating regional SSA offices. At baseline, 89 participants (28%) signed an informed consent to fill out the baseline questionnaire. Of these, 62 participants (19%) returned the follow-up questionnaire.
after four months for the self-reported secondary outcomes (psychological complaints and self-efficacy for RTW). Data regarding the primary outcome duration of sick leave and the secondary outcomes duration of sick leave starting from SSA transfer, number of hours of paid employment during follow-up and degree of participation were available for all workers for the whole six-month follow-up period. An overview of the flowchart of the study is presented in Figure 1.

**Baseline characteristics**

Table 1 presents a summary of the baseline characteristics of the participants in the intervention and control group. At baseline there were no significant differences in characteristics of participants, and in the available characteristics of psychological complaints and self-efficacy for RTW between either group.

**Adherence**

In the Brainwork Intervention group, 112 out of 164 (68%) workers actually received the Brainwork Intervention program. For five workers, priority was given to another intervention. Of the 47 workers in the intervention group who did not receive any intervention, the sickness benefit of 23 workers terminated within two months of the SSA receiving the sick report. In 16 workers of the intervention group (10%), at least three of the five protocol steps were followed, including timely start of the Brainwork Intervention program. In the control group, 43 out of the 156 (28%) workers received a usual care intervention. Of the 113 workers in the control group who did not receive any intervention, the sickness benefit of 16 workers terminated within two months of the SSA receiving the sick report.

**Primary outcome**

**Duration of sick leave**

The mean duration of sick leave in the intervention group was 171 days (SD 61) versus 185 days (SD 86) in the control group, a mean difference of 14 days. The Cox regression analysis, adjusted for SSA office and type of worker, showed an HR of 1.34 (95% CI 0.91–1.97; \( p = 0.14 \)), indicating a non-significant reduction of duration of sick leave in the intervention group compared to the control group. See Table 2 for the Cox regression results. Figure 2 shows the adjusted cumulative hazard curves for the Brainwork Intervention group and the control group. These curves
show the cumulative chance for both groups that the event (termination of sick leave) occurs over time, indicating a shorter duration of sick leave in the Brainwork Intervention group.

**Secondary outcomes**

**Duration of sick leave starting from SSA transfer**
The mean duration of sick leave starting from SSA transfer in the intervention group was 146 days (SD 59) versus 152 days (SD 53) in the control group, a mean difference of six days. The Cox regression analysis, adjusted for SSA office and type of worker, showed an HR of 1.25 (95% CI 0.85–1.83; \( p = 0.26 \)), indicating a non-significant reduction of duration of sick leave starting from SSA transfer in the intervention group compared to the control group. See Table 2 for the Cox regression results. Figure 3 shows the adjusted cumulative hazard curves for the Brainwork Intervention group and control group, indicating a shorter duration of sick leave in the Brainwork Intervention group.

**Number of hours of paid employment during follow-up**
During the six-month follow-up, 41 workers in the intervention group and 43 workers in the control group had paid employment. The mean number of hours of paid employment for those working was 257 hours (SD 261) in the intervention group and 443 hours (SD 304) in the control group (group difference in linear regression, adjusted for SSA office and type of worker: \( p = 0.005 \)). This indicates that for all those working, hours worked in the control group were significantly higher than in the intervention group. Information about contract hours was not available. See Table 2 for the results. When taking all the 320 participants into account, there were no significant differences between the groups.

**Degree of participation**
Ordinal regression analysis revealed an OR of 1.16 (95% CI 0.72–1.86; \( p = 0.55 \); control vs. intervention group), controlling for SSA office and type of worker. This indicates that participation was non-significantly higher in the control group compared to the intervention group.
CHAPTER 7

Figure 1
Flowchart of the study

485 unemployed and temporary agency workers and workers with expired fixed-term contracts eligible for participation

Screening for inclusion criteria

Inclusion in study (n = 320)

Allocation

Baseline questionnaire (n = 51)

- Started Brainwork Intervention program (n = 112)
- Priority given to other intervention (n = 5)
- Did not start any intervention program (n = 47)

Brainwork Intervention group (n = 164)

Control group (n = 156)

Baseline questionnaire (n = 38)

- Usual care Intervention program (n = 43)
- Did not start any intervention program (n = 113)

Main reasons for exclusion (n = 165):
- Expected recovery < 2 weeks or > 12 months
- Physical complaints
- No command Dutch language
- (recent) Pregnancy
- Substance addiction
Figure 1 Flowchart of the study
Table 3 presents the results of the Mixed Model analyses for psychological complaints and self-efficacy for RTW, adjusted for regional SSA office and type of worker. After four months follow-up, although both groups showed a significant decrease in psychological complaints (adjusted mean difference -5.57 for intervention group and -5.27 for control group), the course of the psychological complaints between the two groups did not differ statistically ($p = 0.88$). The self-efficacy for RTW increased in both groups (adjusted mean difference 0.26 for intervention group and 0.16 for control group), but no statistical differences were found between the groups ($p = 0.72$).

### Table 1 Baseline characteristics of non-permanent workers, sick-listed due to psychological problems ($n = 320$)

<table>
<thead>
<tr>
<th></th>
<th>Intervention group ($n = 164$)</th>
<th>Control group ($n = 156$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr (mean ± SD)</td>
<td>$40 ± 10.7$</td>
<td>$40 ± 10.8$</td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>46.3</td>
<td>45.5</td>
</tr>
<tr>
<td>Type of worker (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed/temporary agency worker</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Expired fixed-term contract worker</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Brainwork categorya (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 1</td>
<td>70.6</td>
<td></td>
</tr>
<tr>
<td>Category 2</td>
<td>29.4</td>
<td></td>
</tr>
<tr>
<td>Segmentation codeb (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Code 1</td>
<td>28.7</td>
<td>19.9</td>
</tr>
<tr>
<td>Code 2</td>
<td>71.3</td>
<td>80.1</td>
</tr>
<tr>
<td>Psychological complaints (mean ± SD) (0 to 36 score)</td>
<td>$n = 89$</td>
<td></td>
</tr>
<tr>
<td>$28.4 ± 6.9$</td>
<td>(n = 51)</td>
<td>(n = 38)</td>
</tr>
<tr>
<td>Self-efficacy for RTW (mean ± SD) (1 to 6 score)</td>
<td>$n = 87$</td>
<td></td>
</tr>
<tr>
<td>$3.0 ± 1.03$</td>
<td>(n = 49)</td>
<td>(n = 38)</td>
</tr>
</tbody>
</table>

*Brainwork category 1 = estimated recovery < 3 months
Brainwork category 2 = estimated recovery 3 to 12 months
Segmentation code 1 = estimated sick-leave duration < 13 weeks
Segmentation code 2 = estimated sick-leave duration 13 to 52 weeks

**Psychological complaints, and self-efficacy for RTW**

Table 3 presents the results of the Mixed Model analyses for psychological complaints and self-efficacy for RTW, adjusted for regional SSA office and type of worker. After four months follow-up, although both groups showed a significant decrease in psychological complaints (adjusted mean difference -5.57 for intervention group and -5.27 for control group), the course of the psychological complaints between the two groups did not differ statistically ($p = 0.88$). The self-efficacy for RTW increased in both groups (adjusted mean difference 0.26 for intervention group and 0.16 for control group), but no statistical differences were found between the groups ($p = 0.72$).
### Table 2  Cox Regression and Regression analysis results at 6-month follow-up  \((n = 320)\)

<table>
<thead>
<tr>
<th></th>
<th>Intervention group ((n = 164))</th>
<th>Control group ((n = 156))</th>
<th>Regression coefficient</th>
<th>(P)</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of sick leave(^a), mean (SD) (days)</td>
<td>171 (61)</td>
<td>185 (86)</td>
<td>0.29</td>
<td>0.14</td>
<td>1.34 (0.91 – 1.97)</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration from SSA transfer to RTW(^a), mean (SD) (days)</td>
<td>146 (59)</td>
<td>152 (53)</td>
<td>0.22</td>
<td>0.26</td>
<td>1.25 (0.85 – 1.83)</td>
</tr>
<tr>
<td>Number of hours of paid employment during follow-up(^b), mean (SD) ((n = 84))</td>
<td>257 (261) ((n = 41))</td>
<td>443 (304) ((n = 43))</td>
<td>-184.59</td>
<td>0.005</td>
<td></td>
</tr>
<tr>
<td><strong>Degree of participation(^c)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Odds Ratio(^c)</td>
</tr>
<tr>
<td>No participation (%)</td>
<td>70.7</td>
<td>67.9</td>
<td>0.15</td>
<td>0.55</td>
<td>1.16 (0.72 - 1.86)</td>
</tr>
<tr>
<td>Non-paid work (%)</td>
<td>4.3</td>
<td>4.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paid work (%)</td>
<td>25.0</td>
<td>27.6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) Cox regression analysis adjusted for regional SSA office and type of worker  
\(^b\) Linear Regression analysis of working participants \((n = 84)\) adjusted for regional SSA office and type of worker  
\(^c\) Ordinal Regression analyses adjusted for regional SSA office and type of worker
### Table 3: Results of the mixed model analyses for self-reported secondary outcomes

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline (T1)</th>
<th>4 months (T2)</th>
<th>Group*Time</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Psychological complaints, mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>28.3 (7.1)</td>
<td>22.7 (8.6)</td>
<td>-5.57</td>
<td>(p &lt; 0.01)</td>
</tr>
<tr>
<td>Control</td>
<td>29.2 (7.0)</td>
<td>24.2 (8.5)</td>
<td>-5.27</td>
<td>(p &lt; 0.01)</td>
</tr>
<tr>
<td><strong>Self-efficacy for RTW, mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>3.0 (1.0)</td>
<td>2.2 (1.2)</td>
<td>0.26</td>
<td>(p = 0.15)</td>
</tr>
<tr>
<td>Control</td>
<td>2.3 (1.0)</td>
<td>2.6 (0.98)</td>
<td>0.16</td>
<td>(p = 0.43)</td>
</tr>
</tbody>
</table>

Differences in psychological complaints and self-efficacy for RTW between the Brainwork Intervention group and the control group, adjusted for regional SSA office and type of worker. 

B = regression coefficient.
Figure 2  Cumulative hazard curves for the duration of sick leave in days during the 6-month follow-up for the Brainwork Intervention group and the control group adjusted for regional SSA office and type of worker.
DISCUSSION

This paper presents the effects of a newly developed Brainwork Intervention program at six months follow-up for non-permanent workers who were sick-listed due to psychological problems, compared to usual care. Our study indicated a non-significant reduction of the primary outcome measure duration of sick leave in the intervention group compared to care as usual. The non-significant reduction was also found for the secondary outcome measure duration of sick leave starting from SSA transfer in favor of the intervention group. Among those working during six months follow-up, the number of hours of paid employment during follow-up was significantly higher in the control group. No significant differences between...
the intervention and control group were found with regard to the remainder of the secondary outcomes, i.e., degree of participation, level of psychological complaints and self-efficacy for RTW. Finally, the adherence to the intervention protocol was low (10%) and the tailored Brainwork Intervention was not given at all to 32% of the participants in the intervention group.

In this pragmatic controlled study, we studied the effectiveness of an expert-based intervention program developed by OH professionals of the SSA. While acknowledging the advantages of our pragmatic trial, with a good applicability of the intervention [26] and high external validity [26,27], our design also has some disadvantages, including the low protocol adherence by professionals in the real OH setting. Furthermore, as the Brainwork Intervention is a multi-component intervention, our design does not allow us to evaluate which intervention components are responsible for failure or success. However, there are some possible explanations why the Brainwork Intervention did not show marked differences between the intervention group and the control group. First, in only 10% of the participants in the intervention group were at least three of the five protocol steps followed. This means that in 90% of the participants, most of the steps of the intervention protocol, such as telephone contact with the worker, a face-to-face contact with the vocational rehabilitation counselor, or consultation of the IP, were not executed in time or were not executed at all. An explanation for the low protocol adherence on an organization level is that the work process at the participating SSA offices was not geared to such short lead times between the different steps of the intervention protocol, or due to other organizational constraints. Another explanation on the behavioral level for the low protocol adherence could be that the professionals were not used to working according to a tightly prescribed protocol. Implementation research shows physicians often have problems following practice guidelines or changing their behavior to follow the guideline [28]. Although IPs mentioned that the intervention was not indicated nor necessary for some included participants, we found that in most cases (79%) there was, according to the protocol, no valid explanation or reason for not giving the Brainwork Intervention. A second explanation for the non-significant results is that the intensive vocational counseling did not result in noteworthy reintegration into primary paid work or non-paid work (placement in (temporary)
workplaces), which was hypothesized as one of the essential elements of our intervention to achieve functional recovery and regain control [29]. Insufficient involvement of the workplaces can be regarded as program failure [30]. From another study with sick-listed non-permanent workers, it is known that it is hard to find workplaces (temporary or otherwise) for these workers [31]. A third explanation for the non-significant results could be Brainwork category classification errors, which may have led to an inappropriate (i.e., lighter) Brainwork Intervention program. Brainwork category classification errors are suspected because the expected recovery time of the Brainwork category classification of the worker does not correspond to the estimated sick-leave duration of the segmentation code of the worker. Within the intervention group, the Brainwork category classification 1 (estimated recovery <3 months) was assessed in 70.6% of the participants, while the segmentation code 1 (estimated sick leave <13 weeks) was assessed in 28.7% of the participants (see Table 1). With an accurate assessment of the Brainwork category classification, we would expect percentages of workers with Brainwork category classification 1 to correspond more or less with the percentages of workers with segmentation code 1. Perhaps OH professionals need more training in assessing the Brainwork category classification and to achieve a better protocol adherence. The low protocol adherence and possible inappropriate assessment of the Brainwork category classification of the worker can be regarded as implementation failures. Implementation failure is a common reason for inconclusive or negative findings in intervention studies [30,32].

Due to the low protocol adherence (10%), relevant per-protocol analysis for the primary outcome measure duration of sick leave and secondary outcome measure duration of sick leave starting from SSA was not possible. Given the low number of 16 participants for whom the protocol was followed appropriately, the per-protocol analysis was underpowered. Further, the planned Mixed Models analyses for the outcomes regarding sick-leave duration [22] were not possible at six months follow-up, due to the high number of censored cases. This was because termination of sick leave had not yet occurred in 67% of the cases and these cases had to be censored for the analyses. We applied Cox regression analysis because this analysis technique is more appropriate for the high amounts of censored data.
The strength of this study is the complete and accurate data collection for the whole follow-up period from the SSA database for the primary outcome duration of sick leave and the secondary outcomes duration of sick leave starting from SSA transfer, number of hours of paid employment during follow-up and degree of participation. Consequently, this study has no attrition bias for these outcomes. Deriving these outcomes from the database also leads to a low risk of detection bias, despite the lack of blinding to the sick-listed workers, occupational health professionals and the intervention partners that are allocated to the intervention or control group. A concern regarding the self-reported secondary outcomes in this study is that the response rate of the baseline questionnaire (28%) and questionnaire at four months follow-up (19%) was low, resulting in the power of the study to detect changes in the self-reported secondary outcomes being low. Furthermore, a high percentage of selective non-response can bias the results if more participants with a worse mental health or longer estimated recovery period, compared to the respondents, did not return the questionnaire. However, in our study the non-response analysis with regard to the baseline characteristics and the segmentation code did not show an indication for selective non-response.

Based on our study at six months follow-up, the use of the Brainwork Intervention program cannot be recommended. IPs who intend to use interventions for non-permanent workers must realize that a range of interventions are available, but that little can be said about the effectiveness of these interventions.

**CONCLUSION**

Based on the results of our study at six months follow-up, we conclude that in the short-term the Brainwork Intervention did not show marked differences in favor of the intervention group on any outcome. The adherence of the OH professionals to the protocol was low.
REFERENCES


