RETURN TO WORK OF WORKERS WITHOUT AN EMPLOYMENT CONTRACT, SICK-LISTED DUE TO A COMMON MENTAL DISORDER

AN EVALUATION OF A PARTICIPATORY SUPPORTIVE RETURN TO WORK PROGRAM

LIEKE LAMMERTS

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Return to work of workers without an employment contract, sick-listed due to a common mental disorder

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General introduction

Workers without a permanent employment contract and mental ill health

Sick-listed workers without an employment contract: a vulnerable position in the labor market

Sick-listed workers without an employment contract have a vulnerable position in the labor market. To illustrate this, let us consider the following cases:

> *Danny (43 years old) has worked for several years in a small construction company, located in the east of the Netherlands. When the economic recession worsens, the company receives fewer and fewer new projects. As a result, Danny has to wait longer and longer until he receives his salary, and he often receives less money than was agreed on. Finally, the company goes bankrupt and Danny loses his job. He applies for an unemployment benefit, and starts looking for a new job. However, his previous experience makes Danny feel very insecure about his ability to work. Moreover, the job opportunities are very limited due to the economic recession. As he receives less income than before, Danny can no longer meet his financial obligations, such as paying the rent for the house he shares with his wife and two kids. This causes a lot of stress, which in turn leads to relationship issues between Danny and his wife. Danny feels as if he has lost his old self. As his financial debts increase, his wife decides to leave him. Consequently, Danny becomes even more depressed.*

> *Barbara (38 years old) has worked as a temporary agency worker in several administrative jobs in Amsterdam. She feels most confident in her work when there is a certain daily routine. Therefore, every start at a new company goes along with several challenges, such as finding the best route to work, meeting new colleagues and getting new tasks or responsibilities. Barbara often experiences feelings of anxiety when facing this kind of challenges, but she has not yet succeeded in finding a permanent job. She also feels anxious to lose her job. She fears to make a mistake and to be fired. To avoid making mistakes she checks and double checks her work. In the past, her GP diagnosed an Obsessive Compulsory Disorder.*

Further, she lacks social support from a partner to help her with these complaints. Recently, Barbara started in a new position at a large IT firm. She has to work together with people from different departments, and it feels as if every day she is getting new tasks and responsibilities. Facing these kinds of challenges, her anxiety complaints become worse. After a few weeks, she decides that she is too sick to continue working. Very soon she is replaced by another temporary agency worker.

Danny and Barbara, both having no (permanent) employment contract, experience mental health problems. A recent study indicated that the unemployed, like Danny, have an increased risk of (mental) illness, such as a depressive or an anxiety disorder [1]. Moreover, unemployment seems to be both cause and consequence of mental ill health, resulting in a vicious circle [1,2]. Mixed findings have been reported on the relationship between non-permanent employment and (mental) ill health [3]. A qualitative study of Bosmans et al [4] illustrates how temporary (agency) employment can affect (mental) health negatively, resulting from a high job insecurity, low benefits and poorer prospects, as was the case for Barbara, but also positively, through high flexibility, learning opportunities and freedom of choice. Furthermore, research has indicated that non-permanent workers are not sick-listed more frequently than regular employees [5], or even less often [3,6].

Nevertheless, once they get sick, both non-permanent and unemployed workers appear to have a more vulnerable position in the labor market, compared to permanent employees. Sick-listed non-permanent workers seem to be at risk for longer disability episodes, compared to sick-listed permanent employees [7]. In case their employment contract ends during sickness absence, which was the case for Barbara, the lack of a workplace to return to obviously becomes a major obstacle for return to work (RTW) [8,9]. This absence of a workplace to return to is also a major obstacle for RTW of sick-listed unemployed workers, like Danny. Moreover, long-term sick-listed workers who have no (longer an) employment contract often experience a worse health condition and encounter more psychosocial barriers for RTW compared to long-term sick-listed employees, such as language difficulties, debts, legal proceedings, relationship problems, addiction, social isolation, a lack of social support and care issues [9]. Comparable problems were experienced by

Danny and Barbara. Finally, long-term sick-listed workers without an employment contract are more often low-skilled and have less work experience compared to long-term sick-listed employees [8]. All these characteristics illustrate the more vulnerable position in the labor market of sick-listed workers without an employment contract. For this vulnerable group of workers good occupational health care (OHC), including facilitation of RTW, is very important.

Occupational health care in the Netherlands: lack of return to work interventions for sick-listed workers without an employment contract

In the Netherlands, the Sickness Benefits Act executed by the Dutch Social Security Agency (SSA) provides a social security safety net for sick-listed workers without an employment contract, such as sick-listed unemployed workers, temporary agency workers and workers with an expired fixed-term contract. According to this act, workers like Danny and Barbara can file a sickness benefit claim at the SSA, while in many other countries sick-listing is only possible when an individual is employed. When this claim is approved, the SSA is responsible for the provision of a supportive income, ie, sickness benefit payment. This sickness benefit equals maximally 70% of the last wage. In 2014, about 91 800 sick-listed workers received a sickness benefit from the Dutch SSA . Many sickness benefits provided by the Dutch SSA are granted on the grounds of mental health problems (about 40%) [9].

In the absence of an employer, the SSA is responsible for OHC. Sickness absence counseling and vocational rehabilitation are provided by a team of OHC professionals, consisting of an insurance physician, a labor expert and a RTW coordinator. Communication and cooperation with other healthcare providers often remains limited. The insurance physician is responsible for analyzing the medical issues and for advising the sick-listed worker about recovery and RTW. The labor expert provides vocational support and helps to identify RTW options, resulting in a RTW action plan. The RTW coordinator monitors the full vocational rehabilitation process. Some of these actions, such as the medical problem analysis and formulating a RTW action plan, are obligatory and dictated in the Dutch Improved Gatekeeper Act. In addition, the sick-listed worker can be referred to specialized support, such as work disability-oriented treatment to facilitate recovery of

health, or additional vocational rehabilitation support to reduce the distance to the labor market and/or to facilitate RTW [9]. OHC and sickness benefit payment by the SSA end once the worker reports that he/she is no longer sick or the insurance physician establishes full recovery of workability for the last job of the worker. In the absence of a workplace to return to, ending of OHC and sickness benefit payment can occur without actual RTW of the worker. During the second year of sickness absence, OHC and sickness benefit payment may also end if the insurance physician establishes recovery of workability for adjusted work with earnings equal to the worker's last job. After 18 months of sick-listing, the sick-listed worker can apply for a long-term disability benefit (disability pension) at the Dutch Institute for Employee Benefit Schemes. This is the same as for sick-listed employees.

OHC for sick-listed workers without an employment contract is always complicated by the absence of a workplace to return to and will therefore often not be as successful as OHC for sick-listed employees. Nevertheless, there is still plenty of room for improvement [9]. To illustrate, in 2008 a Dutch cohort study comparing long-term sick-listed workers without an employment contract with long-term sick-listed employees showed that only 53% of the sick-listed workers without an employment contract reported that they had received RTW guidance, compared to 86% of the sick-listed employees. More specifically, the obligatory medical problem analysis and RTW action plan was reported by respectively 22% and 23% of the sick-listed workers without an employment contract, compared to respectively 67% and 63% of the sick-listed employees [8]. In 2011, another Dutch cohort study among long-term sick-listed workers without an employment contract revealed that the Dutch SSA could improve its OHC by facilitating suitable work, by paying more attention to the biopsychosocial barriers for RTW of these sick-listed workers, and by improving the sick-listed workers' participation and responsibility in the RTW process [9]. In this same period, a study by Vermeulen et al [10] showed promising results of a participatory RTW program for unemployed and temporary agency workers, sick-listed 2–8 weeks due to a musculoskeletal disorder. This new RTW program contained many elements as were suggested in the aforementioned cohort study [9]. The participatory RTW program was based on a successful RTW program for sick-listed employees with low back pain [11-13], consisting of a stepwise process to jointly identify and solve obstacles for RTW, resulting in a consensus-based RTW action plan. Vermeulen et al [10] were the first who studied the

effectiveness of this program in the absence of a workplace to return to. Placement in a temporary (therapeutic) workplace with ongoing sickness benefit was added to the original protocol to overcome this major obstacle for RTW. The program resulted in a shorter median duration until sustainable RTW with or without continuing benefits, compared to usual OHC by the Dutch SSA [10].

Although the study of Vermeulen et al [10] showed promising results for these workers with musculoskeletal disorders, evidence-based RTW interventions for a comparable group of workers with mental health problems are still lacking, despite the high prevalence of this type of health complaints. Therefore, it seems worthwhile to investigate whether a similar RTW program would also lead to an improvement in RTW of workers without an employment contract, sick-listed due to mental health problems. However, because the sickness benefit payment might continue during placement in a (therapeutic) workplace, the participatory RTW program evaluated by Vermeulen et al was considered more costly compared to usual care, from the social insurer's perspective [14]. For this reason, it also seems worthwhile to investigate whether the focus could be shifted from placement in a temporary (therapeutic) workplace with ongoing supportive benefit to direct placement in a competitive job.

The international context: increase of flexible employment and mental health related sickness absence

In the last decennia flexible forms of employment, such as temporary employment, globally expanded [3,15]. In Europe, the economic recession of 2008 further stimulated this growth [3]. In the same period mental ill health has become a growing cause of sickness absence and labor market exclusion world-wide [16], resulting in enormous societal costs [16] and individual suffering [17,18]. Mild to moderate mental disorders, such as depressive, anxiety, and stress-related disorders, have been the most common disorders. Because of their high prevalence, these common mental disorders (CMDs) have a large impact on the societal burden [16].

Due to the large impact of CMDs, there has been a growing attention in the international literature for the development and evaluation of interventions that aim to enhance RTW of workers who are sick-listed due to a CMD [19-29]. Nevertheless, the majority of these

RTW interventions do not take into account the changing labor market and assume the presence of a workplace to return to. Furthermore, the mental healthcare sector has not yet been a real partner in the RTW process of sick-listed workers with a CMD [16]. Employment issues are often not addressed (adequately) by healthcare providers, although these issues may have an important effect on mental health. Initiatives from the mental healthcare sector that do facilitate RTW have an almost exclusive focus on patients with the most severe mental disorders [16]. A well-known initiative in this regard is supported employment. Key to this evidence-based approach is direct placement in a competitive job, based on the sick-listed worker's preferences. Other characteristics are intensive collaboration between healthcare providers and employment specialists, and ongoing support for the sick-listed worker and employer during placement in a competitive job. According to the OECD, similar RTW programs need to be developed to address vocational needs of sick-listed workers with a CMD [16].

This illustrates that also from an international perspective there is a need for RTW interventions aimed at workers sick-listed due to a CMD, including those without an employment contract. Moreover, there seems to be a need for RTW interventions that facilitate RTW and incorporate the mental healthcare sector as a partner in the RTW process, ie, through an integrated care approach.

Need for more knowledge about factors that influence return to work

In order to improve RTW of workers without an employment contract, sick-listed due to a CMD, knowledge about factors that influence RTW is needed. The aforementioned studies on OHC for workers without an employment contract [9,10] demonstrate some intervention characteristics that may be effective in improving RTW of these workers. However, to develop adequate RTW policy it is also important to investigate what characteristics of sick-listed workers are likely to influence their RTW. Systematic reviews of the literature reveal that RTW of sick-listed workers with mental health problems is associated with disorder-related characteristics (eg, duration and severity of the disorder), demographic characteristics (eg, age) and work-related characteristics (eg, employment status) [30-32]. Studies included in these reviews most often studied the relationship between RTW and disorder-related factors. This means that knowledge about the influence of non-disorder

related factors is still limited. Furthermore, little is known about the influence of all these factors on RTW in the long run, because of the cross-sectional nature of many of these studies [32]. Therefore, further research is necessary to study longitudinal associations between a broad range of factors and RTW of sick-listed workers with mental health problems. Knowledge about these factors will assist in the development and evaluation of suitable RTW interventions.

Aim of this thesis

The main aim of this thesis is to improve RTW of workers without an employment contract, sick-listed due to a CMD. The sub objectives of this thesis are:

1. To get a broad understanding of factors that in the long run influence sustainable RTW of sick-listed workers with a common mental disorder (CMD).
2. To develop a new participatory supportive RTW program for workers without an employment contract, sick-listed due to a CMD, based on a participatory RTW program, integrated care and direct placement in a competitive job.
3. To evaluate the execution of this new program in practice.
4. To evaluate the effectiveness and cost-effectiveness of the new program in shortening the duration until first sustainable RTW in a competitive job.

To reach these aims associations are studied between biopsychosocial factors and sustainable RTW of sick-listed workers with a depressive and/or anxiety disorder, by using data of a large Dutch cohort study (sub objective 1). Further, a randomized controlled trial (RCT) titled “The Co-WORK study” is carried out, in which the new participatory supportive RTW program is compared with usual OHC for Dutch sick-listed workers without an employment contract (sub objective 2, 3 and 4).

Outline of this thesis

The thesis is organized as follows:

- **Chapter 2** reveals which biopsychosocial factors in the long run are associated with sustainable RTW of sick-listed workers with a depressive or anxiety disorder.
- **Chapter 3** describes the design of the Co-WORK study, including the development of the participatory supportive RTW program and the design of the (cost-)effectiveness and process evaluation.
- **Chapter 4** describes a process evaluation of the new program. This evaluation shows whether the components of the new program were realized in practice and in accordance with the protocol. In addition, the recruitment of participants and professionals and its reach, perceived barriers and facilitators for implementation of the new program, and satisfaction of the sick-listed workers and professionals who participated in the program are evaluated.
- **Chapter 5** provides further insight into the execution of the new program in practice, by presenting stakeholders' perceptions of the function(s) of the new program, and of barriers and facilitators for a successful execution of the program within the Dutch social security sector.
- **Chapter 6** presents the effectiveness of the new program in reducing the duration until first sustainable RTW in competitive employment, compared to usual OHC by the Dutch SSA. Also the effectiveness of the program on secondary outcomes including average working hours, duration until RTW in any type of employment, sickness benefit duration, and perceived physical and mental health and functioning, is presented in this chapter.
- **Chapter 7** describes the economic evaluation of the new program, including a cost-effectiveness, cost-utility and return-on-investment evaluation.
- This thesis closes with a general discussion of the main findings, in **chapter 8**.

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2

Longitudinal associations between biopsychosocial factors and sustainable return to work of sick-listed workers with a depressive or anxiety disorder

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Abstract

Purpose Only a limited number of studies have investigated return to work (RTW) of sick-listed workers with mental health problems, and more knowledge is needed about the influence of non-disorder-related factors. This study aimed to identify longitudinal associations between demographic, personality, disorder-related and work-related characteristics and sustainable RTW of sick-listed workers with a depressive or anxiety disorder.

Methods We used data of a large Dutch cohort study to prospectively study longitudinal associations between biopsychosocial factors and sustainable RTW in two years. Associations were studied by means of univariable and multivariable logistic regression analysis. Participants who were sick-listed at baseline and had a lifetime diagnosis of a depressive and/or anxiety disorder were included in this study (N=215).

Results In two years, 51.6% of the participants returned to work sustainably. Age, household income, extraversion, employment status, skill discretion and job security were significantly ($P \leq 0.05$) associated with sustainable RTW in two years in the univariable analyses. The multivariable analysis revealed significant associations between sustainable RTW and age (OR per 10 years is 0.67, 95% CI 0.47–0.95), household income (OR per 100 Euro's a month is 1.04, 95% CI 1.00–1.08) and being on sickness benefit versus being (self-)employed (OR 0.39, 95% CI 0.20–0.77).

Conclusions In the long run not disorder-related factors, but an older age, the absence of a job and a low household income seem to complicate RTW. Policy and research should focus on facilitators and barriers for RTW of workers with these characteristics.

Introduction

As a result of high rates of long-term sickness absence many countries since the 1990s have aimed to improve return to work (RTW) of sick-listed workers [1]. Mental health problems have been a major cause of these high (long-term) sickness absence rates. In 2012 the OECD reported an increase in the proportion of disability benefits that was granted on the grounds of a mental disorder from 15–25% in the mid-1990s to 30–50% in 2009/10 [2]. In addition, numerous studies have identified the presence or symptoms of mental health problems, like depression or distress, as important risk factors for long-term sickness absence [3-7]. These high rates of long-term sickness absence caused by mental health problems have been an important public health concern, as it affects both the individual and society as a whole [8]. Loss of independence, uncertainty, changed self-perception and changed economic conditions have been reported by sick-listed workers in a qualitative study [9]. For society, mental health problems and related sickness absence often result in high costs. To illustrate, in the US in the late 1990s the economic burden of depression and other mental health problems was already one of the highest in comparison with the burden of other illnesses [10].

Policies aiming to improve RTW of (long-term) sick-listed workers include incentives for employers and employees towards reintegration of sick-listed workers, an increase in employment programs, vocational rehabilitation and stricter requirements for approval of disability claims [1]. Characteristics of sick-listed workers have often been examined in previous research [3-6,11-14]. In order to make policies for RTW succeed, it is not only important to know which workers are more prone for long-term sickness absence, but it is also relevant to consider which characteristics of these sick-listed workers affect their RTW. In his editorial on long term sickness absence, Henderson [8] states that “longer absences are associated with a reduced probability of eventual RTW”. In order to prevent long absences and to facilitate sustainable RTW, policy makers should be aware of factors that have a long-term influence on the (sustainability of) RTW of (long-term) sick-listed workers.

From occupational health practice we know that RTW of sick-listed workers is dependent on several factors, eg, perceived health status, employment history and age of the sick-

listed worker [15]. Different theories, such as the biopsychosocial model, also suggest that the ability to work actually results from a combination of biological, psychological and social factors [16,17]. Systematic reviews of the literature have revealed that only a limited number of studies have investigated factors associated with RTW of sick-listed workers with mental health problems [11,18,19] and more knowledge is needed about the influence of other types of factors than the ones that are disorder-related, such as work-related and personal factors [18,19]. Vlasveld et al [14] found associations between long-term sickness absence and several personality traits, ie, high neuroticism, external locus of control, low extraversion and low conscientiousness. They recommended further research on the influence of personality traits on RTW. The objective of our prospective study was to take all these factors into account and to identify longitudinal associations between a broad range of factors and sustainable RTW in two years of sick-listed workers with a depressive or anxiety disorder, two common mental disorders [20]. In this study we addressed demographic, personality, disorder-related and work-related characteristics.

Methods

Design and procedures

In order to identify factors that are associated with sustainable RTW of sick-listed workers with a depressive or anxiety disorder, data of NESDA ("The Netherlands Study of Depression and Anxiety") was used. NESDA is a Dutch longitudinal multi-site naturalistic cohort study. The aim of NESDA is to study the long-term course of depressive and anxiety disorders among 2981 participants aged 18–65 years. NESDA provides detailed information about the severity, type and duration of the disorder and contains a careful documentation of the participants' work status and current or last profession, the participants' personality traits and demographic characteristics.

At the onset of NESDA, 1701 participants had been shortly before diagnosed with a depressive and/or anxiety disorder. At that point 907 participants had a life-time diagnosis, which means that they had had a depressive or anxiety disorder at least once in their lives, or an increased likelihood to develop a depressive or anxiety disorder, because of their family history or because of sub-threshold depressive or anxiety symptoms. The remaining

373 participants were healthy controls. Participants were recruited from community samples (which were the NEMESIS [21] and the ARIADNE cohorts [22]), through mental healthcare organizations (when newly enrolled at one of the 17 participating centers) and through primary care practices (by using a 3-stage screening procedure). Only two exclusion criteria were used: 1. a primary clinical diagnosis of a psychiatric disorder not subject of NESDA and 2. not being fluent in Dutch. The NESDA study protocol was approved by the Ethical Review Board of participating institutes and all respondents signed a written informed consent. The rationale, objectives and methods of NESDA are described in detail elsewhere [23]. For this study we used baseline data of NESDA (T0), data of the first face-to-face follow-up measurement two years after the baseline measurement (T1), and data of the second face-to-face follow-up measurement four years after the baseline measurement (T2).

In our analysis we included all participants of NESDA who had a lifetime diagnosis of a depressive or anxiety disorder at T0 and who were sick-listed at T0 or T1. For participants who were included on the basis of their sickness absence during T1, the data collected during this measurement moment was considered as baseline data. In case data were missing at T1 but available at T0, these data were used to determine the baseline characteristics of this group. The CIDI (WHO version 2.0) was used by specially trained clinical research staff to determine diagnoses of depressive and anxiety disorders according to the DSM-IV criteria [24]. Employment status and sickness absence were assessed with the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (Tic-P) [25]. Participants had either indicated that they were sick-listed from a paid job for >6 months or that they received sickness benefit. The latter group was included irrespectively of the duration of their benefit. Participants who were >80% occupationally disabled at baseline were excluded, since, according to the Dutch law, these participants can be considered being sustainably occupationally disabled. Other exclusion criteria were: 1. being (early) retired at baseline; 2. being on pregnancy/maternity leave at baseline and/or during the follow-up measurement; 3. no participation in the follow-up measurement; and 4. having been sick-listed for <14 days in the previous six months at baseline. With this threshold of two weeks we differentiated between absenteeism of <2 weeks, most likely related to a cold or the flue, and longer absenteeism that may be caused by a chronic condition [26]. As a

result, 215 participants were included in our study: 176 participants at T0 and 39 participants at T1.

Measures

Dependent variable

The primary outcome measure was sustainable RTW in two years. Sustainable RTW was operationalized as follows: the participant is (self-)employed and has not been long-term sick-listed (>14 days) in the previous six months. Data collected with the Tic-P [25], during T1 and T2 of NESDA, were used to assess the primary outcome.

Independent variables

The selection of independent variables was based on the biopsychosocial model. According to this model, work participation or disability of people with health problems includes a biological, psychological and social dimension [17]. The biological dimension normally refers to the health condition. As there are (often) no biomarkers that indicate the presence or symptoms of mental disorders, work participation of sick-listed workers with mental disorders has no clear biological dimension. However, also mental disorders result in ill health and characteristics of these disorders should be taken into account. The psychological dimension of the biopsychosocial model recognizes the influence of personal factors. The social dimension consists of the social context, pressures and constraints, including characteristics of the working environment [17]. Based on these dimensions, a distinction was made in demographic, personality, disorder-related and work-related characteristics of the sick-listed worker.

Demographic characteristics

The following self-reported demographic characteristics were taken into account: a. gender; b. age (in years); c. education (in years); d. marital/partner status (partner versus no partner); and e. net income of the household in Euros per month.

Personality characteristics

The personality characteristics that were included were: a. neuroticism; b. extraversion; c. openness; d. agreeableness; e. conscientiousness; and f. locus of control. Neuroticism, extraversion, openness, agreeableness and conscientiousness together form The Big 5 personality characteristics. In NESDA the NEO-FFI questionnaire was used to measure these five domains of personality. This questionnaire consists of 12 items per domain, measured on a 5-point Likert response format [27]. Locus of control was assessed by a translated 5-item abbreviated version of the Pearlin Mastery Scale [28], with a range from 5–25. Higher scores on this scale indicate more feelings of mastery.

Disorder-related characteristics

The following disorder-related characteristics were assessed: a. diagnoses of depressive or anxiety disorders (no current depressive or anxiety disorder/current depressive disorder/current anxiety disorder/comorbidity between a current depressive and anxiety disorder); b. severity of depressive symptoms; c. severity of anxiety symptoms; d. duration of depressive symptoms; e. duration of anxiety symptoms; f. use of antidepressants (frequent use versus no or infrequent use); and g. treatment by specialized mental healthcare professionals in the preceding six months (specialized mental healthcare versus no specialized mental healthcare).

In NESDA the CIDI was used to assess the diagnosis of a depressive or anxiety disorder according to the DSM-IV criteria [24]. If a disorder could have been diagnosed within the preceding six months, this was labeled as a current disorder. Severity of depressive symptoms was assessed with the 28-item Inventory of Depressive Symptomatology self-report version [29]. Each item of this questionnaire contains four answer categories that correspond to a score ranging from 0–3. The 21-item Beck Anxiety Inventory [30] was used to measure severity of generalized anxiety and panic symptoms. This questionnaire also uses a 4-point scale ranging from 0–3. The duration of depressive and anxiety symptoms was measured with the Life Chart Interview [31]. Using a calendar event recall method, the participant was asked about the course of complaints. The recall period was five years for participants included at T0 and two years for participants included at T1. Based on the description of the course of complaints, a measure for the duration of

symptoms was constructed. This measure was expressed in percentage of time. During the face-to-face measurements in NESDA also the use of antidepressants was quantified. Use of the medicine for >50% of the days in the preceding six months was coded as frequent use. Besides the use of antidepressants, also more specialized mental healthcare was taken into account. With the use of the Tic-P [25] the number of visits to different specialized mental healthcare professionals was quantified. We differentiated between participants who had >1 contact with a first line psychologist, a social worker, a social psychiatric nurse, an institute for mental healthcare, an independent psychiatrist or a psychotherapist in the preceding six months and participants who had not.

Work-related characteristics

Based on the information about the employment status of the participants at baseline, it was possible to differentiate between participants who had indicated that they were self-employed, participants who had an employment contract, participants who had indicated that they were partly occupationally disabled and participants who were on sickness benefit. In the Netherlands, people who become sick-listed and who have no (longer an) employment contract can apply for a sickness benefit at the Dutch Social Security Agency (SSA). We decided to make a distinction between sick-listed workers who were still employed and sick-listed workers who were on sickness benefit or partly occupationally disabled and therefore had a more vulnerable position on the labor market [32].

In NESDA the Job Content Questionnaire (JCQ) [33] was used at baseline to assess conditions in the current or last workplace. The JCQ consists of five subscales, with a sum score per subscale ranging from 0–1: job demands, decision authority, skill discretion, social support at work and job security. The sum scores of the sub scales were dichotomized based on the median split. As previously done by Holleman et al [34], the median split of job demands and decision authority was used to create a new variable, ie, job strain, which distinguishes people with high job demands and low decision authority from others. In previous research of NESDA the type of current or last profession was constructed using an occupational code provided by Statistics Netherlands (CBS) and additional self-reported information on employment status and supervisory status assessed

with the use of the JCQ [35]. We used this classification to differentiate between blue and white-collar workers.

As a result, the following work-related variables were taken into account: a. employment status (vulnerable worker versus being (self-)employed); b. duration of sickness absence (longer versus shorter than six months); c. skill discretion (high versus low); d. social support at work (high versus low); e. job security (high versus low); f. job strain (job strain versus no job strain); and g. type of current or last profession (blue versus white collar).

Analysis

Missing value analysis

T-tests with groups formed by indicator variables and cross tabulations of categorical and indicator variables were performed to investigate if the pattern of missing data in one variable affected the values of another variable. In addition, the hypothesis that the data were missing completely at random was tested with the Little's MCAR test.

Analysis of associations

Descriptive analyses were used to describe the study population at baseline. Logistic regression analysis was used to determine which factors were associated with sustainable RTW in two years. Univariable logistic regression analysis was performed for all independent variables, with sustainable RTW in two years as the dependent variable. Variables that had a P value of <0.15 in the univariable analysis were entered into a combined multivariable logistic regression model. A cut-off value of $P \leq 0.05$ was used to determine the significance of the associations in the combined model (Wald statistic). Multicollinearity between the variables in the combined model was checked by means of multicollinearity diagnostics. When the resulting VIF scores were >10, multicollinearity was assumed [36]. In addition, correlations between variables were investigated if these variables were likely to measure the same construct. SPSS version 20.0 was used for the statistical analysis.

Results

Characteristics of the study population at baseline

Characteristics of the study population at baseline are summarized in Table 1. More than 90% of all participants were currently diagnosed with a depressive or anxiety disorder at baseline, of which slightly more than half had a combination of a current depressive and anxiety disorder. About three-fourths of all participants was at baseline sick-listed for >6 months. More than half of the participants, 62.3%, could be labeled as a vulnerable sick-listed worker. Most of them, about 98%, had indicated that they were on sickness benefit.

Data about the personality traits, assessed with the NEO-FFI questionnaire and the Pearlin Mastery Scale, were missing for 2–10% of the participants. Data about the work-related characteristics that were measured with the JCQ (skill discretion, social support at work, job security, job strain and type of current or last profession) were missing for 17–33% of the participants. The missing value analysis showed that there was no significant difference between the participants with and without missing values (Little's MCAR test, P=0.186).

Table 1 Characteristics of the study population [a]

Baseline characteristics	
Demographic characteristics	
Sex, % female	66.5
Age (range 20–62), mean (SD)	42.32 (10.53)
Partner status, % partner/married	67.9
Education in years (range 5–18)	11.74 (3.29)
Net income of household in Euros a month (range <600– >5000), mean (SD)	2244.86 (1020.42)
Personality characteristics	
Neuroticism (range 18–57), mean (SD)	41.16 (7.40)
Extraversion (range 15–52), mean (SD)	33.95 (6.88)
Openness (range 24–57), mean (SD)	37.71 (5.90)
Agreeableness (range 28–59), mean (SD)	43.74 (5.20)
Conscientiousness (range 19–57), mean (SD)	40.18 (7.27)
Locus of control (range 5–25), mean (SD)	14.51 (4.20)
Disorder-related characteristics	
Diagnosis anxiety or depression	
no current depressive or anxiety disorder (%)	8.4
current depressive disorder (%)	21.4
current anxiety disorder (%)	16.7
comorbidity between depressive and anxiety disorder (%)	53.5
Severity depression (range 3–58), mean (SD)	32.02 (12.91)
Severity anxiety (range 0–58), mean (SD)	18.41 (11.06)
Percentage of time depressive symptoms (range 0–100), mean (SD)	33.70 (30.83)
Percentage of time anxiety symptoms (range 0–100), mean (SD)	40.52 (35.28)
Use of antidepressants, % frequent use	52.1
Specialized mental healthcare, used by %	76.7
Work-related characteristics	
Employment status, % vulnerable worker	62.3
Sickness absence, % >6 months	73.0
Job demands (range 0–1), mean (SD)	0.54 (0.37)
Decision authority (range 0–1), mean (SD)	0.66 (0.33)
Skill discretion (range 0–1), mean (SD)	0.68 (0.30)
Social support (range 0–1), mean (SD)	0.58 (0.32)
Job security (range 0–1), mean (SD)	0.54 (0.41)
Type of worker	
white collar (%)	77.8
blue collar (%)	22.2

N=Number; SD=standard deviation

[a] N varies between 171 and 215 due to missing cases

Associations with sustainable return to work in two years

In two years, 51.6% of the participants returned to work sustainably. All associations with sustainable RTW in two years, both univariable and multivariable, are summarized in Table 2.

In the univariable analysis the following baseline characteristics had an association of $P<0.15$ with sustainable RTW in two years and were selected for multivariable analysis: age, education, net income of the household, extraversion, conscientiousness, employment status, skill discretion and job security. None of the disorder-related factors was significantly ($P\leq0.05$) associated with sustainable RTW in two years.

In the combined model significant associations were found between sustainable RTW in two years and age, net income of the household and employment status. The odds ratio (OR) for sustainable RTW per 10 years age increase was 0.67 (95% confidence interval (CI) 0.47–0.95), indicating lower odds of sustainable RTW at a higher age. This OR was 1.04 (95% CI 1.00–1.08) per increase of 100 Euros a month in net income of the household, which means that one is more likely to return to work sustainably at a higher household income level. Being a vulnerable worker compared to a (self-)employed worker resulted in a >2 times smaller odds of sustainable RTW (OR 0.39, 95% CI 0.20–0.77). All the VIF-scores in the collinearity statistics for the combined model were <10, so multicollinearity was not assumed.

Table 2 Univariable and multivariable associations with sustainable RTW in two years [a]

Baseline characteristics [b]	Univariable associations [c]			Multivariable associations in combined model [c]		
	OR	95% CI	P	OR	95% CI	P
Demographic characteristics						
Sex, female	0.73	0.41 – 1.28	0.27			
Age (per 10 years increase)	0.71	0.54 – 0.92	0.01	0.67	0.47 – 0.95	0.02
Education (per year increase)	1.08	0.99 – 1.17	0.08	1.01	0.91 – 1.13	0.83
Partner status, partner	1.25	0.71 – 2.22	0.44			
Net income of household (per 100 Euro's a month increase)	1.04	1.01 – 1.07	<0.01	1.04	1.00 – 1.08	0.04
Personality characteristics [d]						
Neuroticism	0.89	0.68 – 1.17	0.41			
Extraversion	1.33	1.00 – 1.75	0.05	1.25	0.87 – 1.78	0.23
Openness	0.92	0.70 – 1.21	0.54			
Agreeableness	1.01	0.77 – 1.33	0.92			
Conscientiousness	1.27	0.97 – 1.68	0.09	1.03	0.71 – 1.49	0.90
Locus of control	1.03	0.78 – 1.37	0.82			
Disorder-related characteristics						
Diagnosis anxiety or depression			0.68			
no current depressive or anxiety disorder	REF	-	-			
current depressive disorder	0.67	0.23 – 2.01	0.48			
current anxiety disorder	0.72	0.23 – 2.23	0.56			
comorbidity	0.97	0.36 – 2.63	0.95			
Severity depression	0.99	0.97 – 1.01	0.19			
Severity anxiety	1.00	0.98 – 1.03	0.92			
Duration of depressive symptoms (per 10% time increase)	0.95	0.87 – 1.04	0.29			
Duration of anxiety symptoms (per 10% time increase)	0.98	0.91 – 1.06	0.68			
Frequent use of antidepressants	1.37	0.80 – 2.34	0.25			
Specialized mental healthcare	1.09	0.58 – 2.05	0.79			
Work-related characteristics						
Employment status, vulnerable worker	0.37	0.21 – 0.66	<0.01	0.39	0.20 – 0.77	<0.01
Sickness absence >6 months	0.75	0.41 – 1.37	0.35			
Job strain	0.97	0.52 – 1.79	0.92			
High skill discretion	1.90	1.05 – 3.46	0.04	1.47	0.73 – 2.98	0.28
High social support	1.45	0.79 – 2.64	0.23			
High job security	2.05	1.11 – 3.78	0.02	1.44	0.71 – 2.92	0.31
Type of worker, blue collar	0.71	0.32 – 1.57	0.40			

N=Number; OR=odds ratio; 95% CI=95% confidence interval

[a] N varies between 171 and 215 due to missing cases

[b] The reference category for each dichotomous variable is the contrast ("female versus male")

[c] Reference category is "no sustainable RTW in two years"

[d] OR's are per SD increase. SD neuroticism is 7.40; SD extraversion is 6.88; SD openness is 5.90; SD agreeableness is 5.20; SD conscientiousness is 7.27; SD locus of control is 4.20

Discussion

Main findings

The aim of this study was to investigate longitudinal associations between demographic, personality, disorder-related and work-related characteristics and sustainable RTW in two years of sick-listed workers with a lifetime diagnosis of a depressive or anxiety disorder. In two years, 51.6% of the study participants returned to work sustainably. This study revealed that in the long run not disorder-related factors, but a younger age, a higher household income level and being (self-)employed are all together associated with a higher odds of sustainable RTW in two years of sick-listed workers with a depressive or anxiety disorder.

Comparison with other studies

Most of the participants in this study had currently been diagnosed with a depressive and/or anxiety disorder at baseline. Earlier research within NESDA reported a twofold and a sevenfold higher risk of long-term sickness absence for persons with respectively an anxiety disorder or depressive disorder in the same period that the disorder was present, so cross-sectional [26]. We selected participants of NESDA for our study, based on their long-term sickness absence. Since participants with a depression had the highest risk of long-term sickness absence, it is not surprising that many of our respondents were diagnosed with a current depression at baseline. Another study within NESDA revealed that persons with a depression are also most likely to have recovered in two years [37]. This might be an explanation for the absence of an association between the presence or severity of the disorder at the moment of sick-listing and RTW two years later. Moreover, our findings confirm that when one's aim is to enhance sustainable RTW of sick-listed workers with mental health problems, it is not sufficient to solely focus on characteristics of the disorder itself, which has often been done in previous studies [18].

The influence of a broad range of factors on RTW has been studied before in study populations consisting of sick-listed workers with physical complaints, such as low back pain. Results of these studies emphasize the importance of work-related factors in RTW, such as job satisfaction, social support, job demands and job control [38-41]. In our study, univariable associations were found between sustainable RTW in two years and two work-

related factors: a high job security and a high skill discretion. However, in the combined model, the associations between sustainable RTW and these work-related factors did not remain significant. This might be explained by the high number of participants that were on sickness benefit at baseline. They probably had no (longer a) workplace to return to, so that characteristics of the job influenced RTW to a lesser extent.

More than half of the participants in our study reported at baseline that they were on sickness benefit. They had a two times lower odds of returning to work in two years than participants who at baseline reported that they were (self-)employed. In the Netherlands, unemployed workers, temporary agency workers and workers with an expired fixed-term contract who become sick-listed can apply for a sickness benefit from the Dutch SSA. Both unemployment and temporary employment have been related to poor (mental) health [11,15,42-44]. Nevertheless, it seems that these workers are not sick-listed more often [45,46], but when they do get sick-listed the absence of a workplace to return to will complicate their RTW importantly [15]. This stresses the need for vocational interventions that create a RTW perspective [47,48], ie, interventions that focus on a suitable job for vocational rehabilitation. As evidence for effective vocational interventions for this vulnerable group of workers is lacking, more research on this topic should be promoted.

Besides the absence of a job to return to, also other obstacles for RTW might explain the reduced odds of sustainable RTW in two years for sick-listed workers on sickness benefit. It is possible that these workers experience a so called “benefit trap”. This means that the perceived (economic) benefits of staying out of work exceed the benefits of returning to work, for example because it is not possible to find a job that pays more than the income from being unemployed or sick-listed [49]. This could also be an explanation for the reduced odds of sustainable RTW in case of a lower household income that was found in this study. A benefit trap might be experienced by the ones with a lower income.

Apart from sick-listed workers without a (permanent) employment contract, also older workers seem to represent a vulnerable group. This study showed that the odds of sustainable RTW of sick-listed workers with a depressive or anxiety disorder decreases significantly per each ten years of age increase. This finding is highly supported by earlier research [7,11,18,19]. As the workforce is ageing, work participation of older workers is of growing importance. Based on an in-depth study of older workers’ perspectives and

previous research, Koolhaas et al [50] proposed a tailor-made intervention with the aim to enhance sustainable working life, with a central focus on work-related problems and obstacles, personal development opportunities and environmental factors. Knowledge about the effectiveness of these kinds of interventions for older workers is needed.

Strengths and limitations

Systematic reviews of the literature have shown that previous prognostic cohort studies more often addressed disorder-related factors, compared to work-related and personal factors, when studying RTW of sick-listed workers with mental health problems [18,19]. To our knowledge this has been one of the first studies that paid equal attention to the long-term influence of demographic, personality, disorder-related and work-related characteristics. This made it possible to study the independent effects of all these different factors and this is an important strength of our study.

A second strength of this study is that longitudinal associations were studied. All independent variables were measured at baseline. At this point all participants were sick-listed. In this way, all independent variables were measured prior to the possible occurrence of the outcome. Longitudinal associations provide more information than associations that are determined in a cross-sectional study, because with only cross-sectional data it is not possible to know whether an independent variable preceded the outcome or not. Moreover, assessing longitudinal associations between RTW and multiple factors, makes it possible to determine which of these factors have a long-term influence on RTW. This provides important information for policymakers who are engaged in the development of RTW policies.

Another strength of the study is that participants with a variety in duration of sickness absence and employment status were included in the study, which made it possible to investigate the influence of sickness absence duration and employment status on sustainable RTW. A disadvantage of our selection of participants is that the study population consists of participants with a probably worse prognosis than the source population of NESDA. Therefore, generalizing these results to other groups, such as workers who are only short-term sick-listed from a paid job, may be limited.

Another limitation of the study was the interpretation of the employment status of participants. In NESDA the Tic-P was used to collect information about the employment status of participants. In this study we assumed that the participants who indicated that they were on sickness benefit had no workplace to return to. In the Netherlands being on sickness benefit usually means that someone has applied for a sickness benefit from the Dutch SSA, because of the absence of an employer. However, as employment status was self-reported by the participants, we are not sure if the participants who had indicated that they were on sickness benefit actually had no (longer an) employment contract. Nevertheless, the sick-listed workers who had indicated that they were on sickness benefit differed significantly in outcome from the sick-listed workers who had indicated that they were (self-)employed.

The outcome measure, sustainable RTW in two years, was also assessed with the Tic-P [25]. This questionnaire uses a reference period of six months. For that reason, it was only possible to know whether the participant had returned to work for a limited period of time (six months). This is a limitation of our study. However, the follow-up period was more than these six months. Our outcome measure was assessed after two years follow-up, with a recall period of six months. As we were interested in return to work on the long run, the assessment of RTW after two years provided us with very valuable information. The measurement of the outcome with the use of the Tic-P did not only show whether someone was at work in two years, but also provided some information about the sustainability of this outcome, because information was available about days of sickness absence in the previous six months.

The varying number of participants in the analysis due to missing values is also a limitation. However, the hypothesis that the values were missing completely at random could not be rejected. Imputation of missing data would probably not have provided new information. For that reason, we decided not to apply any data imputation techniques.

Practical implications and further research

As long-term sickness absence is more and more caused by mental health problems [2], it is for policymakers and occupational healthcare professionals important to know which (modifiable) factors influence sustainable RTW of sick-listed workers with mental health

problems and to anticipate on this. This study reveals that in the long run characteristics of the disorder itself, such as duration and severity, do not influence sustainable RTW. Although work participation of sick-listed workers with mental health problems has still been studied mainly in regard with the disorder itself, there is a growing awareness of the importance of a healthy and steady job. The results of this study indicate that some workers are more vulnerable than others when becoming sick-listed. Especially older workers and workers without a (permanent) employment contract had a reduced odds of sustainable RTW in the long run. This might be explained by social-political factors, such as ageing of the workforce, the availability of jobs in the labor market and the increase of flexible employment relationships [51]. RTW programs and practices should take this larger social-political context into account. Therefore, research aiming to investigate facilitators and barriers for RTW of more vulnerable groups of sick-listed workers can be highly recommended.

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3

Return to work of workers without a permanent employment contract, sick-listed due to a common mental disorder: design of a randomized controlled trial

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Abstract

Background Workers without a permanent employment contract represent a vulnerable group within the working population. Mental disorders are a major cause of sickness absence within this group. Common mental disorders are stress-related, depressive and anxiety disorders. To date, little attention has been paid to effective return to work (RTW) interventions for this type of sick-listed workers. Therefore, a participatory supportive RTW program has been developed. It combines elements of a participatory RTW program, integrated care and direct placement in a competitive job. The objective of this paper is to describe the design of a randomized controlled trial (RCT) to evaluate the cost-effectiveness of this program compared to care as usual.

Methods/design The cost-effectiveness of the participatory supportive RTW program will be examined in a RCT with a follow-up of 12 months. The program strongly involves the sick-listed worker in the identification of obstacles for RTW and possible solutions, resulting in a consensus based action plan. This plan will be used as a starting point in the search for suitable competitive employment with support of a vocational rehabilitation agency. During this process the insurance physician of the sick-listed worker contacts other caregivers to promote integrated care. Workers eligible to participate in this study have no permanent employment contract, have applied for a sickness benefit at the Dutch Social Security Agency and are 2–14 weeks sick-listed due to mental health problems. The primary outcome measure is the duration until first sustainable RTW in a competitive job. Outcomes are measured at baseline and after three, six, nine and 12 months.

Discussion If the participatory supportive RTW program proves to be cost-effective, the social security system, the sick-listed worker and society as a whole will benefit. A cost-effective RTW program will lead to a reduction of costs related to sickness absence. For the sick-listed worker a cost-effective program results in earlier sustainable RTW, which can be associated with both social and health benefits.

Trial registration The trial registration number and date is NTR3563, August 7, 2012.

Background

The need for a return to work perspective

Workers without a permanent employment contract, such as unemployed workers, temporary agency workers and fixed-term contract workers, represent a vulnerable group within the working population. Unemployment seems to be associated with poor health [1,2] and research suggests that flexible work arrangements might share some of these negative consequences for workers' health with unemployment [3]. To illustrate, in their systematic review on temporary employment and health Virtanen et al [4] found evidence for an association between temporary employment and increased psychological morbidity.

In most European countries the non-permanent employment rate has increased during the last two decades [5]. In the Netherlands in 2012 almost a quarter of the active labor force was working on a temporary basis, compared to almost 18% in 2001 [6]. A major reason for the increase in flexible employment relationships is the need for companies to adjust easily to international developments [5]. Also, due to the shrinking Dutch economy in the last couple of years, more people have become unemployed [7].

In the Netherlands, the Dutch Social Security Agency (SSA) is responsible for occupational healthcare (OHC) of sick-listed workers who have no (longer an) employment contract. The SSA carries out the Sickness Benefit Act, which provides supportive income, ie, sickness benefit, for these types of sick-listed workers [8].

In their report of 2011 on characteristics of prolonged sick-listed workers without a permanent employment contract, the Dutch SSA mentioned mental disorders as the most frequently diagnosed disorders among this group [9]. Within the European region mental health problems are increasingly acknowledged as a major public health concern [10,11]. They affect at least one in four people in the European region at some point in their lives [11]. Moreover, a recent study on the mental health consequences of the economic recession in European countries suggests that the impact of loss of employment on people with mental health problems is more severe than on people without mental health problems [12]. In the Netherlands, common mental disorders (CMDs) are stress-related disorders, depressive disorders and anxiety disorders [13,14].

Compared to sick-listed workers with a permanent employment contract, in the Netherlands sick-listed workers without a permanent employment contract perceive their health status more negatively and encounter more psychosocial barriers for their return to work (RTW) [15,16]. Moreover, sick-listed workers without a permanent employment contract experience a greater distance to the labor market compared to sick-listed employees, because there is often no workplace to return to [15]. To date, only little attention has been paid to the development of RTW interventions for sick-listed workers without a permanent employment contract who experience work limitations due to a CMD [17]. The aim of this study was to develop a RTW intervention for this group of sick-listed workers and to investigate the cost-effectiveness of this intervention.

The development of a participatory supportive return to work intervention

The development of a RTW intervention for workers without a permanent employment contract who are sick-listed due to a CMD was based on an already existing participatory RTW program. Key elements of this intervention are active participation and strong commitment of both the sick-listed worker and his supervisor in a stepwise process to identify and solve obstacles for RTW, resulting in a consensus based RTW action plan [18]. We examined the strengths, weaknesses and points for improvement of the participatory RTW program reported in the literature. In addition, important stakeholders were consulted to assess the need for a participatory RTW program for workers without a permanent employment contract, sick-listed due to a CMD. Interviews were held with managers and professionals of the Dutch SSA, representatives of three Dutch rehabilitation agencies and representatives of the Dutch mental healthcare sector. To investigate the needs of the intended target group of the RTW program, results from a survey among 810 sick-listed workers without a permanent employment contract who applied for a sickness benefit at the Dutch SSA were used [16].

Studies on the effectiveness of the participatory RTW program reveal that this program significantly reduced time to RTW of employees 2–6 weeks sick-listed due to low back pain and of employees 2–8 weeks sick-listed due to distress who at baseline intended to return to work despite symptoms, compared to care as usual [19,20]. Vermeulen et al [21] were the first who studied the cost-effectiveness of this program for sick-listed workers

without a permanent employment contract, namely for temporary agency workers and unemployed workers 2–8 sick-listed weeks due to a musculoskeletal disorder. Because these sick-listed workers had no (longer a) workplace to return to, placement in a matching temporary (therapeutic) workplace with ongoing supportive benefit by the SSA was added to the original participatory RTW program. The median duration until first sustainable RTW was 161 days for temporary agency workers and unemployed workers who had received the intervention and 299 days in the usual care group [22].

The results of the study of Vermeulen et al indicate that the participatory RTW program is also an effective RTW intervention for sick-listed workers without a permanent employment contract. However, in this study the SSA paid supportive benefit (from public money) during placement in a temporary (therapeutic) workplace. This made the intervention more costly than usual care from the social insurer's perspective [23]. Therefore, in the present RTW program for sick-listed workers without a permanent employment contract who are sick-listed due to a CMD, the focus has been shifted from placement in a temporary (therapeutic) workplace with ongoing supportive benefit to direct placement in a competitive job. Direct placement in a competitive job has already shown to improve RTW of people with severe mental illness as part of Individual placement and Support (IPS) programs [24,25]. The essence of IPS is to first place in suitable competitive employment and then train by offering personal guidance at the workplace [24,26]. Moreover, results of the survey of Van der Burg et al [16] show that placement in a suitable job during sickness absence positively affected sustainable RTW of sick-listed workers without an employment contract who applied for a sickness benefit.

Another practice that has been incorporated in the present participatory supportive RTW program is an integrated care approach. The participatory supportive RTW program has been developed in line with a Dutch covenant between the SSA and the mental healthcare sector that was signed recently. This covenant has the mutual aim to improve the (occupational) participation of sick-listed workers with mental disorders. The importance of integration of mental and occupational healthcare has also been emphasized in several studies. To illustrate, Olesen et al [27] suggest in their study about mental health and employment that policies to promote and maintain workforce participation should be incorporated in mental healthcare, to prevent social exclusion of the sick-listed worker and

to achieve a more sustainable contribution of this vulnerable group of workers to the labor force. According to a study of Anema et al [28], in the Netherlands communication between occupational health and other healthcare professionals, such as mental healthcare professionals, has been limited. These findings were confirmed by the insurance physicians we interviewed. They acknowledged the importance of collaboration with the caregivers of their clients, but experienced obstacles in approaching these caregivers. In the present participatory supportive RTW program, the insurance physicians are asked to actively involve the caregiver(s) of the sick-listed worker in their advice on RTW possibilities. Communication formats, eg, a letter with a contact request and information about the study, are provided to the insurance physicians to facilitate making contact with the caregiver(s) of the sick-listed worker.

Hence, direct placement in a competitive job and an integrated care approach were integrated into the initial participatory RTW program, resulting in a participatory supportive RTW program aimed for workers without a permanent employment contract who are sick-listed due to a CMD.

Objective

The objective of this paper is to describe the design of a randomized controlled trial (RCT). This study aims to investigate the cost-effectiveness of the participatory supportive RTW program for workers without a permanent employment contract who are sick-listed due to a CMD on the duration until first sustainable RTW in a competitive job, compared to usual OHC.

Methods/design

The design of the RCT will be described following the guidelines for reporting randomized trials provided by the CONSORT statement [29].

Trial design

The study design consists of a RCT with two arms: a control group and an intervention group. Both the control group and the intervention group will receive usual OHC. In

addition, the intervention group will be guided according to the new participatory supportive RTW program. Measurements will take place at baseline and after three, six, nine and 12 months.

Seven front offices of the Dutch SSA, "The Dutch Institute for Employee Benefit Schemes" (in Dutch: "Uitvoeringsinstituut Werknemersverzekeringen"), will participate in the RCT together with three vocational rehabilitation agencies operating on national level. Each participating SSA office will be asked to assign two intervention teams of OHC professionals to participate in the study. These intervention teams will be trained to guide intervention group respondents according to the participatory supportive RTW program.

Randomization will take place at the level of the participant. A separate block randomization table will be generated for each SSA district. Beforehand, the SSA front offices will be divided into three regional districts.

The trial design, procedures and informed consent have been approved by the Medical Ethics Committee of the VU University Medical Centre (Amsterdam, The Netherlands).

Participation in de study will be voluntary and will only be possible when the participant signs informed consent.

A project team will be formed to monitor the conduct of the trial. This project team will consist of the researchers, representatives of the SSA and representatives of the vocational rehabilitation agencies. Towards the stakeholders and participants, the RCT is titled the "Co-WORK" (in Dutch: "SamenWERK") study.

The trial has been registered at the Dutch Trial Register ("Nederlands Trial Register") on August 7, 2012.

Study population

Workers eligible to participate in the study are 2–14 weeks sick-listed workers without a permanent employment contract who have applied for a sickness benefit at the Dutch SSA, eg, sick-listed unemployed workers, temporary agency workers and workers with an expired fixed-term employment contract, in the working age range (18–64 years), with mental health problems as the main reason for their sickness benefit claim.

Earlier research on the effectiveness of a participatory approach suggested that sick-listed workers who believe they should be fully recovered before they return to work, require

another RTW intervention [20,22]. Therefore, not having the intention to return to work in case health complaints are still experienced is an exclusion criterion for participating in this study. Other exclusion criteria are: 1. not being able to complete questionnaires written in the Dutch language; 2. having a conflict with the SSA regarding a sickness benefit claim or a long-term disability claim; 3. the presence of a legal conflict, eg, an ongoing injury compensation claim; 4.a sickness absence episode due to a CMD within one month before the current sickness benefit claim; 5. already having received usual OHC since the start of the current sickness absence period, 6. Pregnancy, up until three months after delivery; and 7. no signed informed consent form.

When the sick-listed worker is allocated to the intervention group, the insurance physician of the intervention team will be asked to investigate any (medical) contra-indications for participation in the participatory supportive RTW program, eg, severe co-morbidity because of a terminal disease, a severe psychiatric disorder, or a serious cardio-vascular disease and/or the absence of work abilities due to medical reasons for ≥3 months. In case of an identified contra-indication, the study participant will not be referred to the participatory supportive RTW program. However, according to the intention-to-treat-principle, the participant will remain in the intervention group.

Recruitment of participants

Workers without a permanent employment contract who have applied for a sickness benefit at the Dutch SSA and are 1–2 weeks sick-listed, will receive an invitation package from the medical advisor of the SSA, on behalf of the researchers. It contains an invitational letter, a flyer with more details about the study, a consent form and a short questionnaire with a return envelope. A weekly query of the SSA database will be used for the recruitment of eligible workers.

The short screening questionnaire consists of six questions. The sick-listed worker will be asked to fill in whether he/she is interested to participate in the study and to indicate the day he/she applied for a sickness benefit. The Distress Screener, developed by van Oostrom et al [30], will be used as a quick scan for early identification of distress, ie, three questions of the 4-Dimensional Symptom Questionnaire (4DSQ) will be used to assess the degree of perceived mental health problems. Finally, the sick-listed worker will be asked whether

he/she has “certainly not/probably not/maybe/probably/certainly” the intention to return to work if health complaints are still experienced.

In case the sick-listed worker wants to participate and meets the eligibility criteria, he/she will be contacted by the researcher or research assistant for a first intake by telephone. During this intake more information about the study will be given. When the sick-listed worker has indicated to “maybe/probably/certainly” have the intention to return to work despite health complaints, the sick-listed worker will be invited to participate in the RCT. Using the described exclusion criteria, the researcher or research assistant will decide whether the sick-listed worker is able to participate.

In case the sick-listed worker is able to participate, an intake appointment will be planned at the nearest participating front office of the SSA. During the intake, randomization will be performed after signing informed consent and fulfilling the baseline questionnaire by the participant.

In Figure 1 the consecutive steps in the study design are summarized.

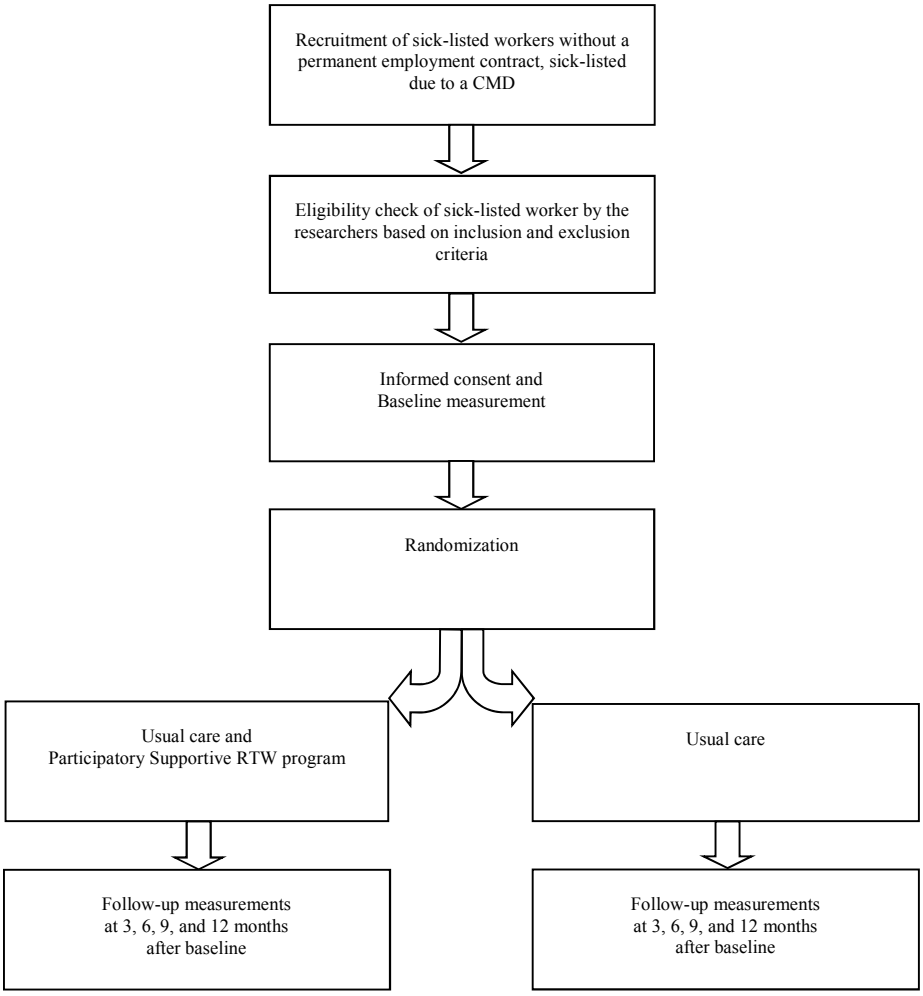

Figure 1 Design of the randomized controlled trial

Usual occupational healthcare

After the sickness benefit application by the sick-listed worker, a RTW coordinator of the SSA will note down the reason for reporting sick and investigates why the sick-listed worker thinks he/she is not able to perform his or her job anymore. An insurance physician of the SSA will decide whether to approve the sickness benefit claim on the basis of a medical assessment. During this assessment, the insurance physician will make a (medical) problem analysis with an advice about recovery, ie, health promotion and RTW possibilities [8].

In case the sickness benefit claim is approved, the insurance physician, the RTW coordinator and a labor expert of the SSA together are responsible for RTW coaching for the duration of the sickness benefit. The sick-listed worker will be guided according to the Dutch guidelines for OHC. He/she is obligated to visit the OHC professionals and to cooperate with regard to recovery and RTW. The sickness benefit will end when the worker is no longer work disabled [21].

The participatory supportive return to work program

The aim of the participatory supportive RTW program is to make a consensus-based action plan to achieve RTW. There are four main stakeholders. These stakeholders are the participant, ie, the sick-listed worker himself/herself, the insurance physician of the SSA, a RTW coordinator of the SSA who guides the vocational rehabilitation process and a labor expert of the SSA who coaches the participant and the RTW coordinator in the development of a RTW action plan.

The labor expert is responsible for equal involvement of both the participant and the RTW coordinator of the SSA in making a RTW action plan with the aim to achieve consensus. Similar process guidance by a trained coach was earlier successfully applied in a participatory RTW program for sick-listed unemployed workers and temporary agency workers with musculoskeletal disorders [31].

Figure 2 gives a schematic overview of the content of the participatory supportive RTW program.

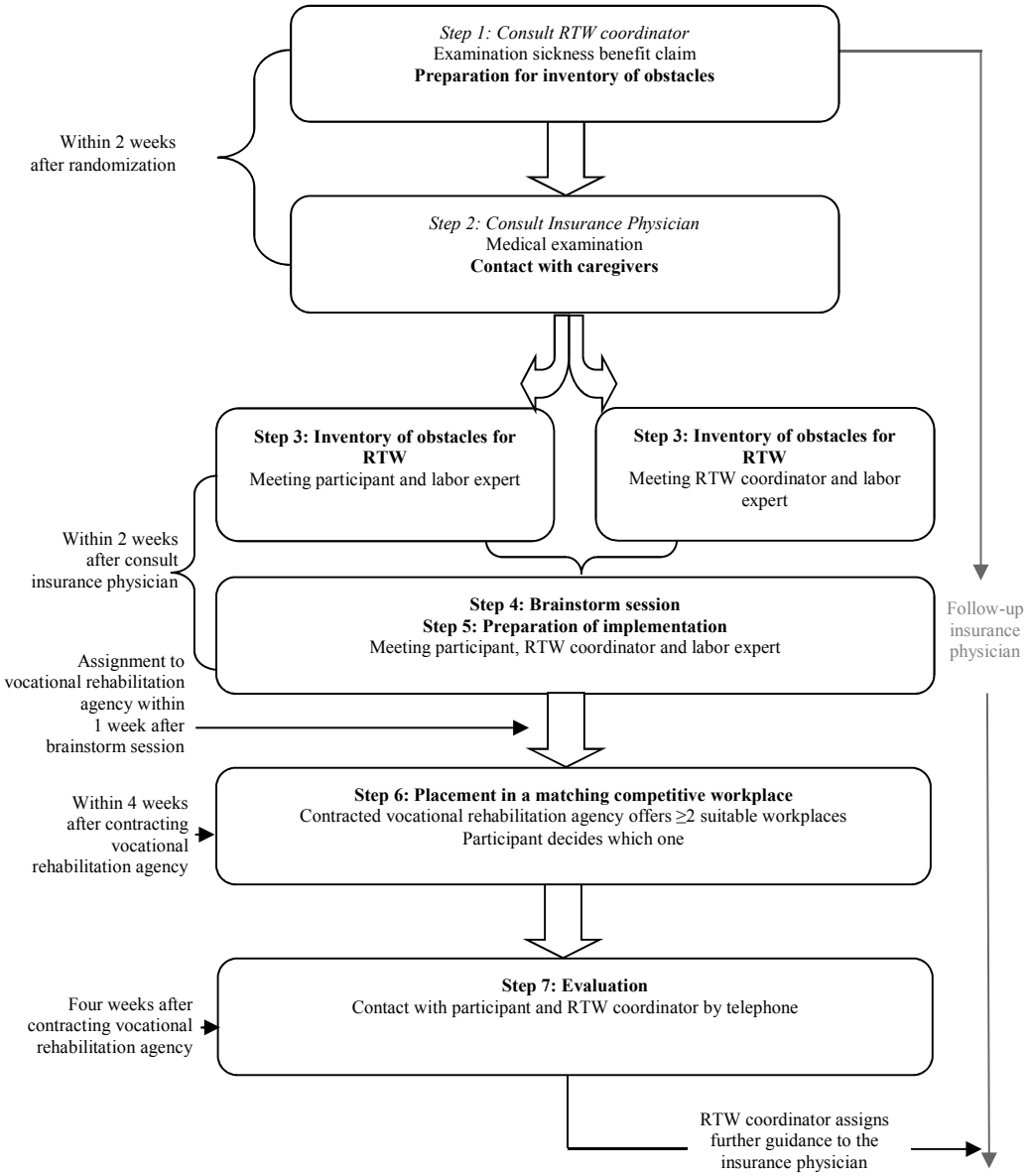

Figure 2 Content of the participatory supportive RTW program

Guidance by the RTW coordinator and insurance physician

Within two weeks after the intake appointment at the SSA, the participatory supportive RTW program will start with an examination of the sickness benefit claim by the RTW coordinator and a medical assessment by the insurance physician conform usual OHC. In addition, the participant will receive a take-home assignment from the RTW coordinator. He/she will be asked to list obstacles for RTW as a preparation for the first meeting with the labor expert. Obstacles can be both work related or non-work related.

A strong cooperation and communication between the insurance physician, the GP and mental healthcare specialists are required. Therefore, the insurance physician will contact the caregivers of the participant right after the first medical assessment by telephone to make sure that the participant is given no conflicting advice and to agree on treatment and RTW options.

Inventory of obstacles for return to work

The goal of the meeting between the participant and the labor expert is to identify obstacles for RTW, from the perspective of the participant. The inventory of obstacles for RTW, filled in by the participant as a take-home assignment, will be used as a starting point. During the identification of obstacles, all aspects of disability should be taken into account, ie, equal attention should be paid to (perceived) biological, psychological and social obstacles [32]. At the end of this meeting the identified obstacles will be prioritized on the basis of frequency and (perceived) severity of the obstacle. In a separate meeting between the labor expert and the RTW coordinator, obstacles for RTW for the participant from the perspective of the RTW coordinator will be identified and prioritized.

Brainstorm session

At the start of the brainstorm session, the labor expert will summarize the three main obstacles identified by the participant and by the RTW coordinator, resulting in ≤6 prioritized obstacles. According to the nominal group technique [18], both the participant and the RTW coordinator will then be asked to think of as many as possible work-related or non-work-related solutions to overcome each prioritized obstacle for RTW. The proposed solutions will be judged on the basis of feasibility to solve the barrier. It is important to

determine who is responsible for the fulfilment of each solution, and when this should be organized and finalized. Subsequently, the participant and the RTW coordinator are asked to think of suitable work, ie, type of work, content and duration of tasks, time path and necessary preconditions. The ultimate goal of this session is to achieve consensus between the participant and the RTW coordinator about solutions to overcome obstacles for RTW and about suitable work.
The inventory of obstacles and the brainstorm session are based on an existing participatory RTW program [18,19,33].

Preparation of implementation

The labor expert will underline the participant's own responsibility to search for suitable work. The formulation of suitable work solutions can help the participant to explore the labor market.
Within two days after the brainstorm session, the labor expert will make a written report of the prioritized obstacles and the consensus-based solutions for RTW, including a concrete work profile in which the content of suitable work tasks, a time path and necessary preconditions are summarized. This action plan for RTW will be presented to the insurance physician who will consider if the proposed suitable work solutions are in line with the physical and mental work capacities of the participant. After comments of the insurance physician have been integrated in the report, it will be sent by the labor expert to the participant, the insurance physician and the RTW coordinator. If necessary, the insurance physician will communicate this action plan for RTW to other caregivers of the participant to promote collaboration.

Placement in a matching competitive workplace

The participant will be supported in the search for a suitable workplace by one of the three rehabilitation agencies that participate in the study. Intervention group participants will be equally assigned to the participating agencies.
After receiving the written action plan for RTW, the RTW coordinator will contact the case manager of the assigned vocational rehabilitation agency and will inform the case manager

about necessary preconditions for RTW. The vocational rehabilitation agency will receive a copy of the action plan for RTW.

Within four weeks, the agency has to offer ≥2 suitable workplaces, with a contract period of ≥3 months, matching with the formulated consensus-based action plan for RTW and taking into account the participant's preferences. The employment contract has to result in ≥50% of the earnings of the participant's last job. Alternatively, placement for a maximum of three months with ongoing sickness benefit is possible, but only when after these three months the employment contract meets the requirements mentioned above. In that case, there should be an intention to offer the participant a (temporary) employment contract. A financial reward will be given by the SSA to the vocational rehabilitation agency for the job hunting and/or for the actual placement in a matching workplace. The participant will be actively involved in the job searching.

The case manager of the vocational rehabilitation agency is responsible for proper guidance of the participant. If required, the case manager will visit the workplace to instruct and advise the participant. And, if necessary, the supervisor and/or colleagues at the workplace can be informed by the case manager about how to guide the participant at the workplace.

Evaluation

Four weeks after the start of the job search by the vocational rehabilitation agency, the RTW coordinator will contact the participant and the case manager of the agency by telephone to inform whether placement in a workplace has been successful. The RTW action plan will be evaluated and, if necessary, the action plan will be adapted to new circumstances. The RTW coordinator summarizes findings in a final report.

In case the assigned vocational rehabilitation agency has not been able to offer a suitable workplace, the other two rehabilitation agencies participating in the project will also get the opportunity to search for suitable vacancies.

Six weeks and three months after placement in a workplace, the case manager of the vocational rehabilitation agency will evaluate the program with the participant, and will send a report with a summary of the most important findings to the RTW coordinator of the SSA.

Training of the professionals

Instruction will be given to all intervention teams by the researchers. At each participating SSA office instruction takes place by means of a presentation and role plays during one session of approximately three hours. In the beginning of this session all professionals will receive a syllabus with detailed information about the program, the protocol, practical summaries and schemes and practice material. A few months after the first participants have enrolled in the intervention, the researchers will visit every participating intervention team for a follow-up session to evaluate the first cases and to discuss difficulties in applying the protocol in daily practice.

Use of co-interventions

Co-interventions cannot be avoided. It is possible that the study participants will receive other interventions. In both the intervention and control group received co-interventions will be monitored in each follow-up measurement.

Outcomes

Effect evaluation

The primary outcome measure is the duration until first sustainable RTW in competitive employment. This is defined as the duration in calendar days from the day of enrolment in the study until first sustainable RTW in a competitive job for ≥28 consecutive calendar days without partial or full recurrence of sickness absence. In line with Crowther et al [25], competitive employment is defined as a full or part-time position held by the worker in a regular work setting, for which payment is received at the market rate.

According to the Dutch Sickness Benefit Act, recurrence of an accepted sickness benefit claim within 28 calendar days after ending of the previous benefit is considered as belonging to the preceding sickness benefit period, on condition that it is due to the same (or related) disorder. Although for sick-listed workers without a permanent employment contract ending of the sickness benefit not automatically results in RTW, it was chosen to mark RTW as sustainable only when the participant returned to work for at least these 28 calendar days.

RTW data, ie, work resumption in regular (paid) work, are registered continuously by the Dutch SSA and will be collected from the SSA database after 12 months follow-up.
In addition, with a self-administered questionnaire the participant will be asked whether he/she has worked in (un)paid labor in the last three months. If the participant did return to work, he/she will be asked to specify the period in which RTW has taken place and the average working hours per week.
Secondary outcome measures are:

- RTW in any type of work

  In addition to the primary outcome measure, the duration until first RTW in any type of work will be measured, ie, paid work, unpaid work and work with ongoing supportive benefit.

- Duration of the sickness benefit period

  For workers without a permanent employment contract, it is possible that the sickness benefit ends, before full RTW is achieved. The worker can be recovered from illness or functional limitations (assessed with regard to last or previous work) without actual RTW, because the worker has no workplace to return to. Therefore, in line with Vermeulen et al [21], the duration of the sickness benefit period will be assessed as well. This is defined as the duration of the sickness benefit from the day of enrolment until ending of the sickness benefit for ≥28 consecutive calendar days. Additionally, the total number of days of sickness benefit during follow-up will be calculated. Awarded sickness benefit claims during follow-up are only included in the calculation when the participant is sick-listed due to the same (or related) mental disorder [21]. Data on sickness benefit will be collected from the SSA database and by self-report of the participants.

- Work status

  Work status is defined as the average number of hours worked per week during the 1-year follow-up. In addition to a self-administered questionnaire, the SSA database will be used to collect this information.

- Severity of mental disorder symptoms

  Severity of mental disorder symptoms will be assessed using the 4DSQ [34].

- Perceived general health status

  Using the Dutch translation of the 36-item Short Form Health Survey (SF-36) [35] perceived general health status will be measured.
- Quality of life

  Quality of life will be measured using the Dutch translation of the Euroquol questionnaire [36].
- Attitude, Social Influence and self-Efficacy (ASE) regarding RTW

  For the development of earlier participatory RTW programs the Attitude-Social influence-self-Efficacy (ASE) model was used as an underlying theoretical framework [37,38]. In these studies the ASE constructs were assessed using a questionnaire developed by Van Oostrom et al [39]. In this study we will make use of the same questionnaire.
- Work limitations

  Work limitations will be measured with the Dutch translation of the Work Limitations Questionnaire (WLQ) [40].

Prognostic measures

Demographic characteristics, information regarding last work, type of worker before reporting sick and reason for reporting sick will be assessed with a self-administered questionnaire at baseline.

At the same time, the way health complaints influence vocational rehabilitation will be assessed. This will be measured with questions belonging to the subscale "Fear-avoidance beliefs" of the Dutch Work Reintegration Questionnaire (WRQ) [41,42].

During follow-up, in case full RTW is not (yet) achieved, RTW expectations are measured. With a self-administered questionnaire, participants will be asked to indicate the period within they think it is possible to achieve full RTW (in "own" work or other).

In addition, in each questionnaire participants will be asked whether they received RTW coaching by the SSA and whether they were treated for their health complaints. In case the participant indicates that he/she received RTW coaching by the SSA, questions will be asked about efforts made by the SSA to reintegrate the participant, eg, investments in education or training and contracting a vocational rehabilitation agency. The participant

will be asked to rate the efforts of the SSA on a scale of 1–10. Also, when applicable, the participant will be asked to describe the treatment for his/her health complaints.

Economic evaluation

Direct and indirect costs will be measured to conduct an economic analysis from the social insurer's perspective and the societal perspective.

Costs for healthcare utilization, OHC and investments in vocational rehabilitation support made by the SSA are considered as direct costs. Examples of investments made by the SSA are training or education, interventions aimed at health promotion and contracting a vocational rehabilitation agency to search for a workplace.

Indirect costs are related to paid sickness benefits. In case an employee becomes sick-listed, loss of productivity is normally considered to be part of the indirect costs. However, because sick-listed temporary agency workers, unemployed workers and workers with an expired fixed-term employment contract no longer have an employment contract, loss of productivity does not result in indirect costs [23]. Unemployed workers and workers whose employment contract ended during sickness absence have no workplace (anymore), which means there is no loss of productivity. The sick-listed temporary agency worker will, in case of sick-listing, be replaced with a healthy worker, which results in no productivity loss for the company concerned.

Data on paid sickness benefits and costs for investments made by the SSA will be collected from the SSA database and the worker's files after one year follow-up. Data on OHC by the SSA professionals, ie, number of consults during follow-up and type of OHC professional, will be collected from the SSA database and the medical files. Healthcare utilization will be measured by the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (Tic-P) [43]. The Tic-P is developed to measure healthcare utilization of people with mental illnesses. It quantifies the number of visits to different healthcare providers. Prices for different healthcare services suggested in guidelines for economic evaluation in the Netherlands will be used to value the healthcare consumption [44].

Process evaluation

Based on the framework of Steckler and Linnan [45] a process evaluation will be conducted. The aim of the process evaluation is to determine the compliance with the intervention protocol, the feasibility of the participatory supportive RTW program and to assess satisfaction with the OHC guidance in accordance to this program. Three months after the participant has been assigned to the intervention group, the participant, the OHC professionals of the intervention team and the case manager of the vocational rehabilitation agency will all receive a questionnaire. The OHC professionals and the case manager of the vocational rehabilitation agency will be asked whether the intervention was applied according to the protocol. Additionally, they will be asked about applicability, compliance, satisfaction and barriers regarding implementation of the participatory supportive RTW program. Also the participants will be asked about their satisfaction with the participatory supportive RTW program. These questions are based on the Patients Satisfaction with Occupational Health Services Questionnaire (PSOHSQ) [46] and will be included in the three months questionnaire.

During the participatory supportive RTW program, standardized schemes will be used by the OHC professionals to describe identified barriers for RTW, the formulated solutions, the resulting consensus-based action plan for RTW and a final report. These schemes will be used to collect additional data about the implementation of the participatory supportive RTW program.

An overview of the measures and measurement instruments, including a time path for all measurements, is presented in Table 1.

Table 1 Overview of measurements and time path

Measurement	Time path				
	Baseline (T0)	3 months (T1)	6 months (T2)	9 months (T3)	12 months (T4)
Prognostic measures					
Demographic characteristics (eg, age, gender)	X				
Last work (shifts, hours)	X				
Type of worker before reporting sick	X				
Reason reporting sick	X	X			
Interference of complaints (WRQ)	X				
RTW expectations	X	X	X	X	X
RTW interventions	X	X	X	X	X
Satisfaction with OHC	X	X	X	X	X
Healthcare interventions	X	X	X	X	X
Primary outcome measure					
Duration until first sustainable RTW	X	X	X	X	X
Secondary outcome measures					
Duration of sickness benefit	X	X	X	X	X
Work status	X	X	X	X	X
Severity of mental disorder symptoms (4SDQ)	X		X		X
Perceived general health status (SF-36)	X		X		X
Quality of life (Euroqol)	X		X		X
ASE determinants (ASE questionnaire)	X		X		X
Work limitations (WLQ)			X		X
Healthcare utilization (Tic-P)	X	X	X	X	X
Patient satisfaction*(PSOHSQ)		X			

WRQ=Work Reintegration Questionnaire; OHC=Occupational healthcare;
4SDQ=4-Dimensional Symptom Questionnaire; SF-36=36-item Short Form Health Survey; ASE=Attitude, Social influence and self-Efficacy; WLQ=Work Limitations Questionnaire;
Tic-P=Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness;
PSOHSQ=Patients Satisfaction with Occupational Health Services Questionnaire
*Patient satisfaction with occupational healthcare services is only measured in the intervention group (as part of the process evaluation).

Data collection

The baseline questionnaire will be filled in during the intake appointment at the SSA, after signing informed consent. All other questionnaires will be filled in online, unless the participant prefers to receive a hard copy by postal mail.

Participants will receive questionnaires at baseline and after three, six, nine and 12 months.

In case questionnaires will not be returned within two weeks after the questionnaire is sent, the researcher will contact the participant by telephone to inform whether the participant has been able to complete the questionnaire and to ask the participant, if possible, to complete the questionnaire timely. In case the participant returns the questionnaire, but the received questionnaire is incomplete, the researcher will also contact the participant by telephone. The remaining questions will be repeated by the researcher, so that the questionnaire can be completed by the participant.

In addition to the questionnaires, after one year follow-up data regarding RTW, sickness absence, diagnosis, OHC interventions and investments made by the SSA will be obtained from the SSA database and the medical file of the worker at the SSA. These data will be checked with the self-reported information in the questionnaires.

Sample size

Time to first sustainable RTW in a competitive job is the primary outcome measure for the power calculation. Based on a recent study on a participatory RTW intervention for temporary agency workers and unemployed workers with musculoskeletal disorders [22] a Hazard Ratio (HR) of 2.0 is assumed to be the minimal clinical and societal relevant ratio. This indicates that the participants in the intervention group return to work twice as quickly compared to the participants in the control group. Furthermore, it is assumed that a minimum of 2/3 of the participants will achieve first sustainable RTW during the first 12 months of the follow-up period [22]. Based on a power of (1-β=) 0.80 and a 2-sided significance level of 0.05 (α) a sample size of 100 participants (N=2x50) is needed. Next, potential clustering of cases guided by the same team of OHC professionals is taken into account. To correct for potential clustering of cases an ICC of 0.05 is used and the minimal number of teams is assessed: eight teams of OHC professionals who are trained in guidance according to the participatory supportive RTW program and eight teams of OHC

professionals who deliver only usual OHC. Furthermore, based on comparable research [47], a loss to follow-up of 20% is expected. This results in a requisite number of 172 participants (N=2x86).

Randomization procedure

Randomization will take place on participant level. In line with previous research by Vermeulen et al [21] pre-stratification of participants is based on information about type of worker before reporting sick, ie, unemployed worker, temporary agency worker or fixed-term contract worker. To ensure an equal distribution of control group participants and intervention group participants in the three different SSA districts, participants will also be pre-stratified on district-level. Schemes with random permuted numbers will be used by the principal investigator to generate separate block randomization tables with fixed block sizes of four.

Randomization takes place during the intake appointment at the SSA office. After the informed consent form is signed and the baseline questionnaire is completed by the participant, the assistant of the SSA contacts the research assistant at the VU Medical Center to perform the randomization. The research assistant of the VU Medical Center uses the block randomization table of the correct stratum to determine the randomization result. The participant will be informed immediately about the randomization result, intervention or control group, and the consecutive steps. Participants who are allocated to the intervention group will be assigned to an intervention team of the corresponding SSA office for guidance according to the participatory supportive RTW program in combination with usual OHC. These intervention teams will not be involved in the guidance of control group participants. Control group participants will be assigned to a team of the corresponding SSA office that is not familiar with the intervention program.

Blinding

The OHC professionals who perform the intervention cannot be blinded for the allocation of participants to the intervention group, because they will need to know when to apply the intervention. Also the OHC professionals who are not trained in the participatory supportive RTW program will be informed when a participant is allocated to their team for

usual OHC. Randomization of participants will take place on participant level and participants of both the control group and the intervention group will receive OHC by OHC professionals working at the same office. Therefore, blinding the professionals for the randomization result is impossible.

Because participants need to be informed at least briefly about the content of usual OHC and the participatory supportive RTW program before they are able to sign an informed consent, they can as well not be blinded for the randomization result. Also blinding the participants for the outcome measures will be impossible, as most of the outcomes are self-reported. Bias caused by a lack of blinding will however be limited for the measurement of the duration until first sustainable RTW, the primary outcome measure of this study, and the duration of the sickness absence period, as in addition to the questionnaires the SSA database will be used to measure these outcomes.

To guarantee blinded analyses of the collected data by the researcher, the data will be entered into a database by a research assistant using a unique research number for each participant.

Contamination

Since the intervention teams will not be involved in the guidance of control group participants, contamination will be limited. However, since trained and non-trained OHC teams are working at the same department, non-trained professionals could still be influenced in their usual practice by the intervention teams. Contamination of usual care and the participatory supportive RTW program may also appear when participants have already received usual OHC before they are assigned to the intervention group. Therefore, sick-listed workers who have already received usual OHC cannot participate in the study.

Statistical analysis

After randomization, participants will remain in the group (intervention group or control group) they are allocated to, according to the intention-to-treat-principle. Descriptive statistics will be used to check for dissimilarities of prognostic factors in the two groups at baseline. If necessary, analysis will be adjusted. A comparison of intention-to-treat-analysis

with per-protocol analysis will be used to determine whether protocol deviations might have caused bias. All statistical analysis will be performed at participant level.

Effect evaluation

The duration until first sustainable RTW in a competitive job in both groups will be described by using the Kaplan-Meier method. The Cox proportional hazard model will be used to estimate differences in RTW between the intervention group and the control group, expressed in HR for sustainable RTW and the corresponding 95% confidence intervals. Differences between both groups in total number of days at work and total days of sickness benefit during follow-up will be analyzed with a general linear model. Differences in other secondary outcome measures will be analyzed with the use of longitudinal random coefficient analysis. Clustering of participants within the OHC teams will be taken into account.

Economic evaluation

Cost-effectiveness will be assessed from both the social insurer's perspective and the societal perspective by dividing the incremental costs by the incremental effects. The incremental cost-effectiveness ratio represents the additional costs needed to gain one extra unit of effect in the intervention group compared to the control group. Cost-utility will be measured by dividing the differences in total costs by the difference in quality-adjusted life years between the two groups.

A cost-benefit analysis will be conducted from the societal perspective. The net monetary benefit will be calculated by subtracting the difference in total costs between the two groups from the differences in productivity gain. Return on investment will be measured by dividing the incremental benefit (gain minus costs) by the incremental costs of the investment.

Bootstrapping will be used to estimate uncertainty surrounding the incremental costs. Confidence intervals (95%) around the mean costs differences will be computed by bias corrected and accelerated bootstrapping.

Discussion

The participatory supportive RTW program combines elements of a participatory RTW program, integrated care and direct placement in a competitive job in order to improve the RTW of workers without a permanent employment contract who are sick-listed due to a CMD. The cost-effectiveness of the participatory supportive RTW program will be examined in a RCT. This paper describes the study design.

Strengths of the study

An important strength of the study is that it pays attention to sick-listed workers without a permanent employment contract who experience more barriers for RTW compared to sick-listed employees. Moreover, the participatory supportive RTW program was specifically tailored to an important diagnose group, namely the CMDs.

A second strength of the study is that it is a pragmatic RCT, as the intervention is performed in daily practice. Another strength is that the study includes a process evaluation to determine the feasibility of the participatory supportive RTW program within the Dutch SSA system and satisfaction with this program. Because the RCT is conducted in daily practice and a process evaluation is included, the study will provide important information for possible future implementation of the RTW program.

Finally, the collection of data on RTW and duration of sickness benefit via the SSA database can be seen as an important strength of the study. This minimizes possible bias that can be caused by self-report of the participants and the OHC professionals.

Limitations of the study

A first limitation of the study is that generalizing the results of the cost-effectiveness of this program to other countries can be difficult, especially in countries where sick-listing is not possible without an employment contract. The participatory supportive RTW program is specifically tailored to the Dutch context. In the Netherlands the SSA is responsible for sickness absence counselling of sick-listed workers who have no (longer an) employment contract.

Secondly, because of pragmatic reasons the follow-up period of participants is one year after enrolment in the study. To measure (long-term) cost-effectiveness of the intervention, a longer follow-up period would have been more preferable.

A third limitation is the absence of a pilot study prior to the RCT. A pilot study could have provided important information on how the program's activities fit in the daily activities of the OHC professionals at the Dutch SSA. In addition, a pilot study would have provided more information about the feasibility of placement in a suitable and competitive workplace by the participating vocational rehabilitation agencies. As an alternative, interviews were held with different representatives of the SSA to gather information about the daily practice within their department and about the different occupational roles within the teams of OHC professionals. In addition, during the training in the participatory supportive RTW program, the professionals were asked if there were any flaws in the intervention program that could harm a successful implementation. Small adaptations were made to improve the practicability of the program. Also the representatives of the vocational rehabilitation agencies were asked to judge the feasibility of their role in the participatory supportive RTW program on the basis of their experience with job hunting in de Dutch labor market.

The OHC professionals and the participants will not be blinded for the group allocation in the RCT, which can be seen as another limitation of the study. Because of the allocation of participants of both groups to separate teams of OHC professionals working at the same SSA office, blinding of these professionals will not be possible. Prior to the randomization, participants will be informed about the nature of usual OHC and the participatory supportive RTW program, so that they can give an informed consent. Therefore, blinding of the participants for the randomization result will not be possible either.

Finally, the study population is limited to sick-listed workers who have at baseline the intention to return to work despite their health complaints. Earlier research on the effectiveness of a participatory RTW approach already indicated that sick-listed workers who believe they should be fully recovered before they return to work require another intervention approach [20,22]. Little is known about successful RTW interventions for sick-listed workers who do not intend to return to work if they still face health complaints. For that reason, we will conduct a separate cohort study to identify prognostic factors for the duration until RTW for this particular group.

Impact of study findings

In order to overcome an important obstacle for the RTW of most sick-listed workers without a permanent employment contract, which is the absence of a workplace to return to, placement in a competitive job was incorporated into the RTW program. In the field of OHC research direct placement in a competitive job has been extensively evaluated as part of IPS programs for the severely mentally ill. IPS has been robustly validated by research in the United States [24,25,48] and receives growing attention in Europe [49]. This study will increase knowledge about the effectiveness of this approach for workers who are sick-listed due to less severe and more common mental disorders.

Moreover, the results of this RCT on the cost-effectiveness of the participatory supportive RTW program will demonstrate whether this program is effective in improving RTW of a vulnerable group of sick-listed workers and whether it will outweigh the societal costs and the expenditures made by the Dutch SSA. Current figures of the Dutch SSA show that sick-listed workers without a permanent employment contract run a greater risk of a long term disability claim compared to sick-listed employees [7], resulting in high costs related to disability benefit payment. Mental disorders are the most frequently diagnosed disorders within this group [9]. Henderson states in his editorial on long term sickness absence that this longer absence is associated with a reduced probability of eventual RTW and relates this to subsequent social and economic deprivation [50]. If the participatory supportive RTW program proves to be cost-effective, the social security system, the sick-listed worker and society as a whole will benefit. For social security and society, a cost-effective RTW program will lead to a reduction of costs related to long term sickness absence. For the sick-listed worker a cost-effective RTW program results in earlier sustainable RTW, which can be associated with both social and health benefits [26].

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Process evaluation of a participatory supportive return to work program for workers without a permanent employment contract, sick-listed due to a common mental disorder

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Abstract

Purpose This study aimed to perform a process evaluation of a participatory supportive return to work program for workers without a (permanent) employment contract, sick-listed due to a common mental disorder. The program consisted of a participatory approach, integrated care and direct placement in a competitive job. Our main questions were: were these components realized in practice and in accordance with the protocol? The evaluation took place alongside a randomized controlled trial.

Methods The study population consisted of workers who filed a sickness benefit claim at the Dutch Social Security Agency, professionals of this agency and of vocational rehabilitation agencies. We focused on sick-listed workers and professionals who had actually participated in the intervention. Data was collected mainly by questionnaires.

Results Only 36 out of 94 intervention group participants started with the program. In half of these cases application of integrated care was reported. Most other steps in the program were completed. However, fidelity to the protocol was low to reasonable. Much delay was observed in the execution of the program and only two sick-listed workers were placed in a competitive job. Still, satisfaction with the participatory approach was good.

Conclusions Despite the positive evaluation of the participatory approach, the full program was executed less successfully compared to similar programs evaluated in earlier studies. This will probably affect the outcomes of our trial. Findings from this study will help to interpret these outcomes. Nevertheless, more knowledge is needed about experiences of stakeholders who participated in the program.

Trial registration NTR3563.

Introduction

Sick-listed workers without a (permanent) employment contract, such as sick-listed unemployed workers, temporary agency workers and workers with an expired fixed-term employment contract, often face more obstacles for return to work (RTW) compared to sick-listed employees, especially when there is no (longer a) workplace to return to [1,2]. Mental health problems are frequent reasons for sickness absence within this group [3]. As both the non-permanent employment rate and the absolute number of unemployed workers have increased during the last decade [4,5], RTW of these workers is a growing concern. With the aim to improve RTW of workers without a (permanent) employment contract who are sick-listed due to a common mental disorder (CMD), we developed the participatory supportive RTW program. We evaluated the cost-effectiveness of this program, compared to usual occupational healthcare (OHC), in a randomized controlled trial (RCT) [6].

The participatory supportive RTW program is a complex intervention, consisting of various components and involving different stakeholders. The program combines a participatory approach, in which the sick-listed worker is encouraged to develop an action plan for RTW, direct placement in a competitive job and integrated care. In the absence of an employer, the Dutch Social Security Agency (SSA) is responsible for RTW guidance of sick-listed workers who have no (longer an) employment contract. Different OHC professionals of the SSA were involved in the program. Vocational rehabilitation agencies were contracted in order to support the sick-listed workers in searching for a suitable (competitive) workplace.

Because of the complexity of the participatory supportive RTW program, it was important to get insight into the extent to which the program was executed as planned [7]. A process evaluation is a useful method to describe the extent to which components of the intervention are realized in practice [7], to distinguish between components of the intervention [8], to learn about barriers and incentives for future implementation of these components [9], to get insight into perceptions of stakeholders [8] and to assess the quality of the intervention [7]. A process evaluation enables researchers to interpret the results of the (cost-)effectiveness evaluation of an intervention [7,8,10]. Moreover, it helps to decide which intervention components should be implemented and which components need some improvement [10]. This is of great importance for people who have to reflect on the

(cost-)effectiveness of an intervention, as well as for those who have to decide on implementation of the program in practice.

The aim of the present study was to evaluate the process of the participatory supportive RTW program. Despite the fact that process evaluations of RTW programs have become more common [11-14], this is one of the few studies that investigated the accomplishment of a RTW program in a non-regular work setting, namely in the absence of an employer [13]. Therefore, the present study will contribute to a more comprehensive view on the feasibility of RTW programs.

Our main research questions were: which components of the participatory supportive RTW program were realized in practice and to which extent were these components executed according to the protocol? We also evaluated the procedures used to attract sick-listed workers and professionals for participation in the RCT and their reach, perceived barriers and facilitators for RTW and for implementation of the participatory RTW program and satisfaction of the sick-listed workers and professionals who participated in the program.

Methods

This process evaluation was conducted alongside a RCT on the (cost-)effectiveness of a participatory supportive RTW program for workers without a (permanent) employment contract who were sick-listed due to a CMD, "The Co-WORK" (in Dutch: "SamenWERK") study. This study was approved by the Medical Ethics Committee of the VU University Medical Center and was registered at the Dutch Trial Register ("Nederlands Trial Register") on August 7, 2012 (NTR3563). All participants in the Co-WORK study signed informed consent. The study design has been described in detail elsewhere [6].

Based on the components of a process evaluation defined by Linnan and Steckler, we assessed five components: recruitment, reach, dose delivered, dose received and fidelity [7]. In addition, we investigated barriers and facilitators for RTW and for implementation of the program and we evaluated the satisfaction of sick-listed workers and professionals who participated in the program. Below is described how these components were operationalized.

Study population

The study population consisted of workers without a (permanent) employment contract who were sick-listed due to a CMD, OHC professionals of the Dutch SSA and case managers of vocational rehabilitation agencies.

Sick-listed workers

Eligible for participation were unemployed workers, temporary agency workers and workers with an expired fixed-term employment contract, who had applied for a sickness benefit at the Dutch SSA. They had been 2–14 weeks sick-listed, with mental health problems as the main reason for their sickness benefit claim. Sick-listed workers could not participate if one or more of the following exclusion criteria was present: 1. not being able to complete questionnaires written in the Dutch language; 2. a conflict with the SSA regarding a sickness benefit claim or a long-term disability claim; 3. the presence of a legal conflict, eg, an ongoing injury compensation claim; 4. a sickness absence episode due to a CMD within one month before the current sickness benefit claim; 5. already having received usual OHC since the start of the current sickness absence period; 6. pregnancy, up until three months after delivery; 7. no signed informed consent form; and 8. no intention to return to work before recovery from symptoms. The latter exclusion criterion was based on findings of two earlier studies, which had revealed that sick-listed workers who believe they should be fully recovered before they return to work, require another RTW intervention [15,16].

Occupational healthcare professionals

All participating OHC professionals were working at an SSA front office and participated in the study within an intervention team. These intervention teams consisted of ≥1 insurance physician, labor expert and RTW coordinator. All teams were trained in the participatory supportive RTW program by the researchers. They also received a syllabus with the intervention protocol and practical schemes.

Case managers of vocational rehabilitation agencies

The participating vocational rehabilitation agencies were all certified commercially operating agencies. At each agency one case manager was appointed. These case managers received a detailed instruction for the placement of intervention group participants in a competitive job.

The participatory supportive return to work program

In the participatory supportive RTW program, the insurance physician, labor expert and RTW coordinator of the SSA together with the case manager of the vocational rehabilitation agency supported the sick-listed worker in the development of a consensus-based RTW action plan and in his or her search for a suitable job. Active participation by the sick-listed worker in the program was stimulated. The labor expert monitored the development of the RTW action plan and was responsible for a safe environment in which the sick-listed worker should feel free to come up with suggestions for achieving return to work. A summary of the consecutive steps of the program is presented in Table 1. The program was based on an existing participatory approach [11] (step 3, 4, and 5). An integrated care approach (step 2) and direct placement in a competitive job (step 6) were added to the initial protocol in order to prevent conflicting advice on RTW by different healthcare professionals and to create a RTW perspective. A comprehensive description of the program and its development, can be found in the study protocol [6].

Table 1 The participatory supportive RTW program

Steps	Explanation
Step 1. *Consult RTW coordinator*	The RTW coordinator examines the sickness benefit claim The sick-listed worker receives a take-home-assignment to list and prioritize obstacles for RTW
Step 2. *Consult insurance physician* Within 2 weeks after allocation to the intervention team	The insurance physician performs a medical assessment The insurance physician contacts the sick-listed worker's healthcare provider(s) in order to agree on RTW options
Step 3. *Inventory of obstacles for RTW*	The labor expert supports the sick-listed worker in identifying and prioritizing obstacles for RTW, from the sick-listed worker's point of view The labor expert supports the RTW coordinator in identifying and prioritizing obstacles for RTW, from a professional point of view
Step 4. *Brainstorm session* Within 2 weeks after meeting the insurance physician	The labor expert summarizes the 3 main obstacles for RTW identified by the sick-listed worker and the 3 main obstacles identified by the RTW coordinator The sick-listed worker and the RTW coordinator think of solutions to overcome each obstacle for RTW The sick-listed worker and the RTW coordinator think of suitable work The labor expert tries to reach consensus between the sick-listed worker and the RTW coordinator about solutions and suitable work The labor expert summarizes the proposed solutions and suggestions for suitable work in a RTW action plan
Step 5. *Preparation for implementation* Within 1 week after the brainstorm session	The insurance physician considers whether the RTW action plan is in line with the physical and mental work capacities of the participant Comments of the insurance physician are integrated into the RTW action plan The labor expert sends the final action plan to the sick-listed worker, RTW coordinator and insurance physician The labor expert underlines the sick-listed worker's own responsibility in the search for suitable work The labor expert refers the sick-listed worker to a vocational rehabilitation agency for support in the search for a suitable job
Step 6. *Placement in a matching competitive workplace* Within 4 weeks after contracting the vocational rehabilitation agency	The case manager offers the sick-listed worker ≥2 suitable workplaces The sick-listed worker is placed in a suitable workplace
Step 7. *Evaluation* Four weeks after contracting the vocational rehabilitation agency	The RTW coordinator contacts the sick-listed worker and the case manager of the vocational rehabilitation agency to inquire if the sick-listed worker has found/been placed in a suitable workplace The sick-listed worker will be supported in the job search by 2 more vocational rehabilitation agencies, in case the first agency has not been able to place the participant in a suitable job Support in the job search will be continued for 2 more months The case manager of the vocational rehabilitation agency informs the RTW coordinator on the progress of the job search/placement in a suitable job

Data collection

Three months after randomization and allocation to the intervention group, the intervention group participant, the assigned OHC professionals and the case manager of the contracted vocational rehabilitation agency, all received a questionnaire. Participating professionals were asked to indicate which steps of the participatory supportive RTW program had been realized and when. All stakeholders were asked about barriers and facilitators for RTW and for implementation of the program, using a predefined list of possible complicating and facilitating factors, and about their satisfaction with the different components of the program. In addition, participants were asked to evaluate the extent to which they felt that they had been taken seriously by the participating professionals, based on the Patient Satisfaction with Occupational Health Services Questionnaire (PSOHSQ) [17]. Participating professionals were asked to fill out the questionnaire only when the participant had actually started with the participatory supportive RTW program and were asked to inform the researchers when this did not happen.

In addition, written reports were examined, such as the RTW action plans and reports by the vocational rehabilitation agencies. Furthermore, we used data of the baseline questionnaire of the Co-WORK study to give an overview of the characteristics of the intervention group participants at entry into the study [6]. For the evaluation of the recruitment and reach of the Co-WORK study the SSA database was used. In case information was missing, we contacted the responsible participating professional, in order to complete the information.

Process measures

Recruitment

We defined recruitment as the procedures used to attract sick-listed workers, teams of OHC professionals, and vocational rehabilitation agencies for participation in the Co-WORK study. We described these procedures and illustrated the flow of sick-listed workers in the recruitment process.

Reach

At the level of sick-listed workers, reach was defined as the proportion of the target population that had actually participated in the Co-WORK study, including both intervention and control group participants. The target population consisted of all sick-listed workers who had been approached for participation in the study and had been eligible for participation, based on the in- and exclusion criteria. Reach was also investigated at the level of the OHC teams. Information was registered about the front offices of the Dutch SSA that had been approached for participation in the study and the front offices and teams of OHC professionals that actually had participated in the study.

Dosage

We combined the dose delivered and the dose received in one evaluation component, the dosage. This component was defined as the extent to which the steps of the participatory supportive RTW program had been completed in practice. We determined for each step in the program in how many cases this step had been completed. Only participants who had actually started with the program were included in these analyses.

Fidelity

At a general level, fidelity was defined as the extent to which the participatory supportive RTW program had been implemented according to the protocol. We registered for each participant, which steps of the program had been completed (two points per step). One point was given for fulfillment of the first two steps in the program, as these steps consisted of usual OHC. One point was subtracted in case a step had been completed, but not according to the protocol. By using this scoring system, illustrated in Table *A1* (Appendix), it was possible to calculate an overall fidelity score per participant. In case no information was available about the completion of a certain step in the program, no score was given for this step and also no point was subtracted. We defined a score of 0–9 as low fidelity, a score of 9–15 as reasonable fidelity, and a score of 15 as the highest fidelity. A score of 9 could mean that all steps of the program were realized in practice, but not according to the protocol. Therefore, this score was used to differentiate between low and reasonable fidelity. We counted the number of participants in each of the three fidelity categories. In

addition, we calculated a mean overall fidelity score, by adding up all overall scores and by dividing this by the number of participants. Only participants who had actually started with the program, were included in these analyses.

To get more insight into the timing of the program in practice, we assessed the duration between the steps of the program in the study and compared this to the maximum duration between these steps according to the protocol.

In addition, we assessed the quality of the three basic intervention components in practice, ie, integrated care, a participatory approach and direct placement in a competitive job. To assess the quality of the integrated care performed (step 2), we registered the number of cases in which the insurance physicians had contacted the healthcare provider(s) of the participant according to the protocol, which was by telephone.

To assess the quality of the participatory approach (step 3, 4 and 5), we evaluated the content of the written RTW action plans. The International Classification of Functioning, Disability and Health (ICF) was used to classify the identified obstacles for RTW described in the RTW action plans. The ICF is a classification system for (problems in) human functioning [18]. It distinguishes between body functions and structures, activities and participation and between problems that may arise in these three domains of functioning, which are respectively: impairments, activity limitations and participation restrictions. These different domains of human functioning interact with the person's health condition on the one hand, and environmental and personal factors on the other hand [18]. An obstacle for RTW should either be described as an activity limitation or a participatory restriction, as it has to be clear how the obstacle limits the sick-listed worker to function in work. Subsequently, we registered the number of RTW action plans that contained high quality solutions. In line with Anema et al [11] the quality of these solutions was assessed by determining whether the solutions were related to the perceived obstacle, a person had been made responsible for fulfillment of this solution, and a timetable for implementation was reported. We also investigated whether the solution had been described clearly, ie, as a measurable action. Finally, suggestions for suitable work were explored, by investigating the extent to which the RTW action plans contained clear descriptions of suitable work and relevant preconditions for RTW.

The quality of the support by the vocational rehabilitation agencies (step 6) was assessed by determining the mean number of suitable jobs offered to each participant. Moreover, for each participant who had been placed in a workplace, we investigated whether this placement met the prescribed criteria for placement in a suitable competitive job, ie, an employment contract of ≥3 months resulting in ≥50% of the salary of the participant's last job.

Barriers and facilitators for realization of return to work and implementation of the program

We made an overview of frequently reported barriers and facilitators for realization of RTW. We also described how the investments by the different stakeholders had influenced the execution of the program, according to these stakeholders.

Satisfaction and experiences

For each of the three basic intervention components, the most frequently reported experiences by the different stakeholders were described. In addition, it was investigated how satisfied the participants had been with the guidance by the professionals who had participated in the program.

Data analysis

Descriptive statistics (SPSS 20.0 and Excel 2010) were used to analyze the data. For the evaluation of obstacles for RTW, we developed a coding system. Each component of the ICF model was given a different color. These colors were used to code the obstacles for RTW that were written in the RTW action plans. The coding of obstacles was done by the first author and repeated by a research assistant. Disagreements were discussed in order to achieve consensus.

Results

Recruitment

Sick-listed workers

Table 2 presents the recruitment procedures that were used to attract sick-listed workers for participation in the Co-WORK study. The aim was to include ≥168 sick-listed workers in the study. Between March 2013 and September 2014, 9822 sick-listed workers were approached for participation, based on a weekly query of the SSA database. Figure 1 illustrates the flow of sick-listed workers in the Co-WORK study. One important adjustment was made during the recruitment phase. From the end of 2013, the SSA decided to no longer register the reason for sick-listing, in case the sick-listed worker mentioned this reason. From then on, it was no longer possible to recruit participants based on a registered health complaint. Instead, every newly sick-listed worker belonging to one of the participating SSA offices received the invitation package.

Table 2 Procedures for recruitment of sick-listed workers in the Co-WORK study

Recruitment procedures	Explanation
1. Invitation by Dutch SSA	Workers without a (permanent) employment contract who had applied for a sickness benefit at the SSA because of mental health problems and were belonging to one of the participating SSA offices, received an invitation package from the medical advisor of the SSA 1–2 weeks after sick-listing The package included an invitational letter, a flyer with information about the study, a consent form for contact, a screening questionnaire and a return envelope The sick-listed workers were invited to fill out the forms, and send these back to the researchers
2. First check of eligibility by screening questionnaire	The returned screening questionnaires were assessed by the researcher or a research assistant for a first check of eligibility
3. Screening for in- and exclusion criteria by telephone	The sick-listed workers with a positive screening result were contacted by the researcher by telephone to give more information about the study and to screen for (other) in- and exclusion criteria Sick-listed workers who were screened positive and were willing to participate, were invited to an intake meeting at the SSA
4. Intake meeting at SSA office	Prior to the intake meeting, the sick-listed workers received a brochure with detailed information about the study procedures The sick-listed worker was included in the study, after signing informed consent and completion of the baseline questionnaire After inclusion, randomization and allocation of the sick-listed worker to the control- or intervention group was performed

SSA=Social Security Agency

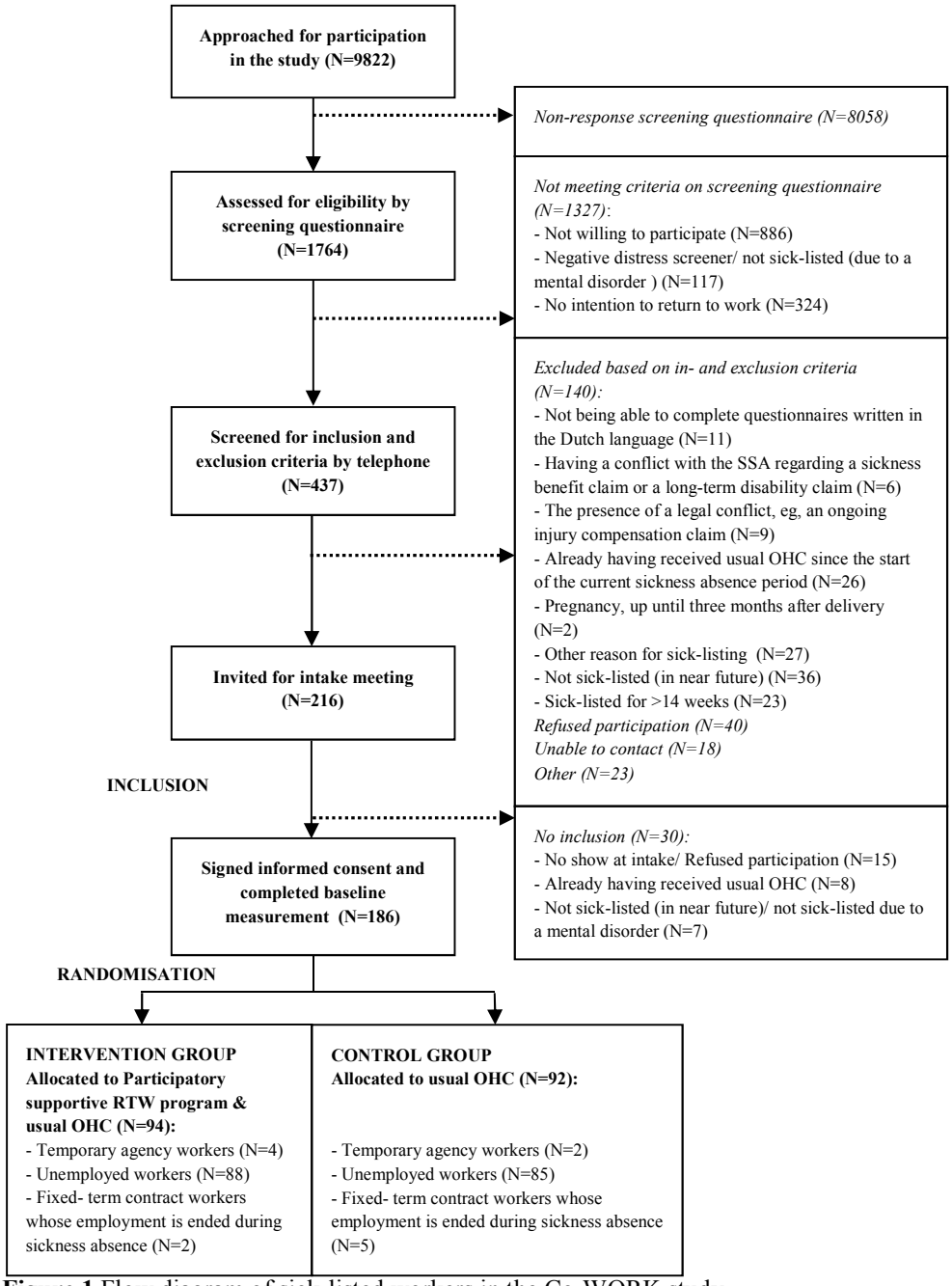

Figure 1 Flow diagram of sick-listed workers in the Co-WORK study

Occupational healthcare professionals

The boards of nine front offices of the Dutch SSA were approached by the researchers for participation in the Co-WORK study. Each office was asked to form two intervention teams, of which one could serve as a back-up in the situation that the other team was (temporarily) not able to participate in the program. In most cases, the manager invited two existing teams of OHC professionals to participate in the study. In case one of these teams was not willing to participate, another team was approached.

Case managers of vocational rehabilitation agencies

Based on performance indicators, the SSA contracted three commercially operating vocational rehabilitation agencies.

Reach

Sick-listed workers

Figure 1 shows that of the 9822 approached sick-listed workers, 619 sick-listed workers were not eligible to participate in the study due to a negative distress screener, an exclusion criterion or for another reason. Of the remaining 9203 sick-listed workers, 186 were included in the study, indicating a reach of 2%. However, due to a change in recruitment procedures, 7310 sick-listed workers had received an invitation for the study while the SSA had not registered their reason for sickness absence. Many of them would probably not have been eligible to participate, because they were sick-listed for other reasons than mental health problems. An estimation of the actual reach should be based on information about sick-listed workers who had been approached before the recruitment procedure was changed. In total, 2512 sick-listed workers had been approached based on registered mental health problems of which 265 were not eligible to participate in the study. Of the remaining 2247 sick-listed workers, 94 participated in the Co-WORK study (49 intervention and 45 control group participants), resulting in an estimated reach of 4%.

Occupational healthcare professionals

Seven out of nine SSA front offices were willing to participate, corresponding to a reach of 78%. The (perceived) time investment was the main reason for the other offices not to participate. At two offices, only one intervention team was formed. Each team consisted of ≥1 insurance physician, labor expert and RTW coordinator. At the start of Co-WORK, 13 insurance physicians, 12 labor experts and 16 RTW coordinators participated in the study. During the study, one insurance physician, one labor expert and one RTW coordinator were (temporary) replaced by a new professional, because they found a new job/were not willing to participate anymore because of the time investment/were on sickness benefit.

Dosage

Of the total group of 186 participants in the Co-WORK study, 94 participants had been allocated to the intervention group based on randomization. The flow of sick-listed workers in the participatory supportive RTW program is illustrated in Figure 2. Of the 94 intervention group participants, 36 participants (38%) had actually started with the participatory supportive RTW program. Main reasons for not starting with the program were the presence of a (medical) contra-indication and ending of the sickness benefit claim (in the near future). Table 3 describes the baseline characteristics of the participants that started with the program and of the total group of intervention group participants. There were no significant differences between the intervention group participants who had actually participated in the program and those who had not.

Most steps of the program were completed in many cases, which corresponds to a high dosage. However, the application of an integrated care approach was reported in slightly more than half of the cases. In some cases, information was missing about the execution of a certain step. Information about the application of integrated care was missing in eight cases (step 2), about the inventory of obstacles for RTW between the labor expert and the participant in three cases and between the labor expert and the RTW coordinator in five cases (step 3), about the brainstorm session in four cases and about the creation of a RTW action plan in two cases (step 4) and about the number of workplaces offered in three cases (step 6).

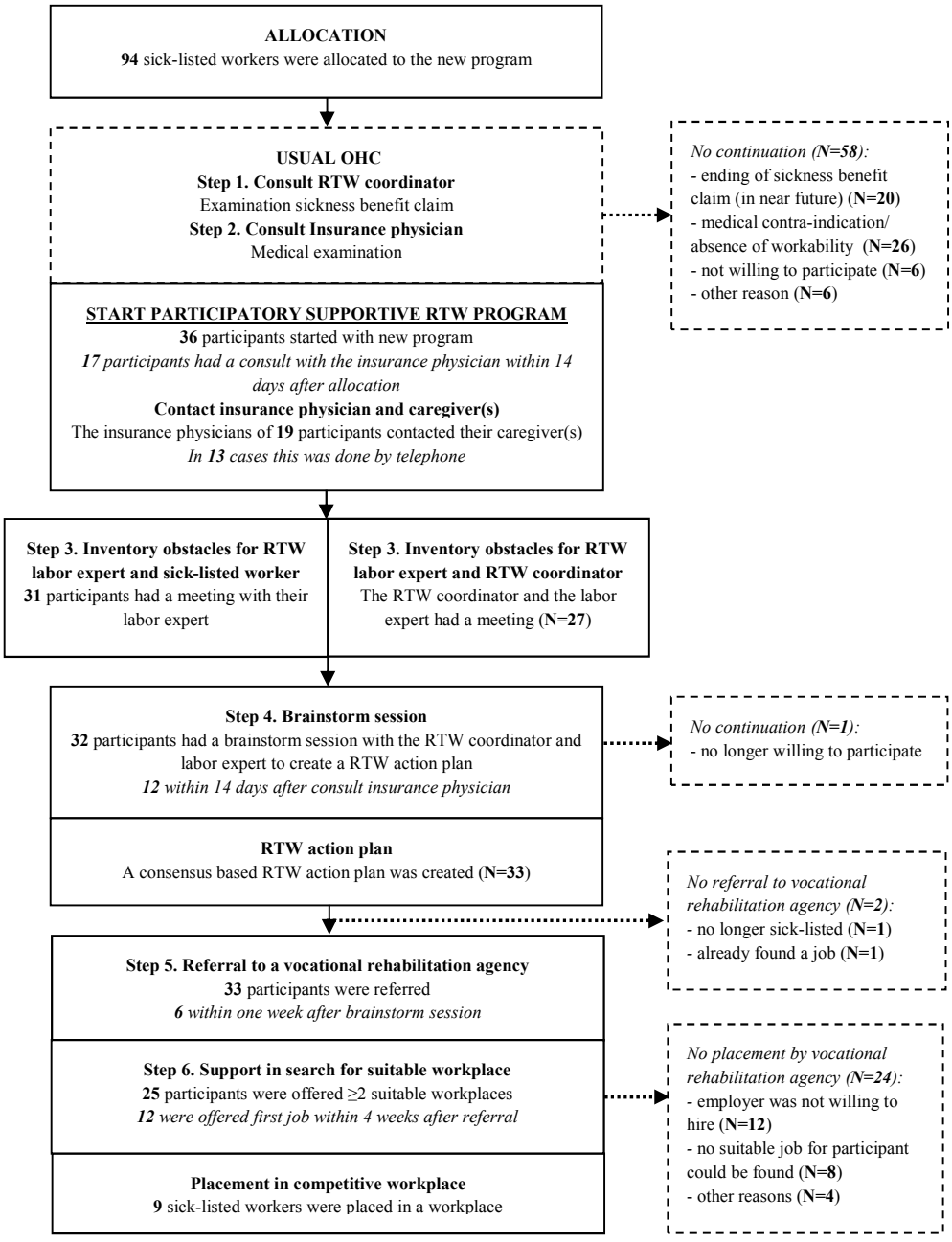

Figure 2 Flow diagram of sick-listed workers in the participatory supportive RTW program

Table 3 Baseline characteristics

Variable	All intervention group participants (N=94) [c]	Intervention group participants who actually participated in the intervention (N=36)
Gender, N (%) Female	45 (48%)	18 (50%)
Age in years, mean (SD)	45.7 (10.6)	44.3 (9.1)
Type of worker		
N (%) unemployed worker	88 (94%)	34 (94%)
N (%) temporary agency worker	4 (4%)	1 (3%)
N (%) fixed-term contract worker whose employment ended during sickness absence	2 (2%)	1 (3%)
Education [a]		
N (%) low	26 (28%)	10 (28%)
N (%) Middle	50 (53%)	20 (56%)
N (%) High	18 (19%)	6 (17%)
Temporary employment contract in last job, N (%)	60 (64%)	24 (67%)
Work schedule in last job		
N (%) day work	72 (77%)	28 (78%)
N (%) irregular work/flexible schedules	18 (19%)	7 (19%)
N (%) shift work	4 (4%)	1 (3%)
Working hours per week in last job, mean (SD)	32.6 (11.6)	34.3 (9.0)
Years worked in last job, mean (SD)	10.0 (10.0)	8.3 (9.8)
4DSQ [b]		
Distress scale score , mean (SD)	25.8 (5.1)	25.8 (4.6)
Depressive scale score, mean (SD)	6.6 (3.7)	6.3 (3.3)
Anxiety scale score, mean (SD)	10.7 (6.0)	10.4 (5.8)
Somatic scale score, mean (SD)	14.9 (6.0)	15.7 (6.2)

N=Number; SD=Standard deviation

[a] Low educational level included no education, primary school or lower vocational education; middle educational level included intermediate vocational education or secondary school; high educational level included higher vocational education or university

[b] Range distress scale is 0–32; range depression scale is 0–12; range anxiety scale is 0–24; range somatization scale is 0–32

[c] N varies between 92 and 94 due to missing cases

Fidelity

General level

In 14 of the 36 cases (39%) in which the participatory supportive RTW program had been implemented, the fidelity of the application of the program by the intervention providers was low (overall fidelity score 3–9). In the remaining 22 cases (61%), the fidelity was reasonable (overall fidelity score 9–14). The mean overall fidelity score was 8.9 (Standard deviation=2.2).

Table 4 shows that the mean and median duration between the steps in practice were mostly longer than the prescribed duration by the protocol. In some cases the program was greatly delayed or postponed.

Table 4 Timing of the participatory supportive RTW program

Steps	*Duration of intervention (in days) according to* Protocol	Practice (study)			
	(Max)	Mean	Median	SD	Range
Allocation to intervention team →					
Consult insurance physician (N=35)[a]	14	33.7	15.0	38.7	1–144
Consult insurance physician →					
Brainstorm session (N=31)[a]	14	26.0	20.0	21.5	1–80
Brainstorm session →					
Referral to vocational rehabilitation agency (N=29)[a]	7	16.7	14.0	13.8	1–62
Referral to vocational rehabilitation agency →					
First suitable job offered by agency (N=22)[a]	28	25.6	25.0	18.8	2–84

N=Number; SD=Standard deviation

[a] N differs from number of participants that participated in these steps, due to missing data

Integrated care

In 13 of the 19 cases (68%) in which the insurance physician reported that he/she had contacted the participant's healthcare provider(s), the insurance physician had contacted the healthcare provider(s) by telephone.

Participatory approach

Eight out of 33 written RTW action plans (24%) contained ≥1 description of an activity limitation or participation restriction, such as the inability to cope with high workload, deadlines or complex issues or a restriction in the available working hours. Most of the RTW action plans (N=27) contained a description of a personal characteristic, without explaining how this characteristic formed a barrier for RTW. Likewise, in some RTW action plans mental health problems were described, without linking this to RTW. Sometimes only a few words were given instead of a description of an obstacle for RTW. In a few cases a solution was described, instead of an obstacle. The most frequently reported obstacles for RTW were "uncertainty or low self-esteem" (N=12), "trouble concentrating" (N=8), "mental health problems" (N=6), "restriction in available working hours" (N=3) and "worry" (N=3).

Almost all RTW action plans (N=32) contained ≥1 solution related to the perceived obstacle(s). In all action plans was described who was responsible for the fulfillment of ≥1 solution. A timetable was present for ≥1 of the solutions in 28 action plans (85%). In 25 action plans (76%), ≥1 of the solutions was described clearly.
In nine RTW action plans (27%), both descriptions of suitable work and job examples were given. In 12 RTW action plans (36%) only descriptions of suitable work were given, such as less demanding work, and in ten action plans (30%) only examples of a suitable job were listed, eg, "postman" or "mechanic". In two action plans (6%) suitable work was not described. Preconditions for work resumption were mentioned in 26 action plans (79%), eg, step-wise work resumption and support of a colleague or supervisor at the workplace.

Direct placement in a competitive job

On average, each of the participants had been offered three workplaces by the first agency the participant had been referred to. Of the nine workplaces in which participants were placed, only two met the criteria for placement in a suitable workplace.

Response on questionnaires for process evaluation

Of the 36 participants who had actually started with the participatory supportive RTW program, 31 had filled out the 3-month follow-up questionnaire (86%). A questionnaire had been filled out by the RTW coordinators in 30 out of 36 cases (83%), by the insurance physicians in 28 cases (78%), the labor experts in 27 cases (75%) and the case managers of the vocational rehabilitation agencies in 21 cases (58%). Sometimes questions could not be answered (yet) at the time of the process evaluation, because execution of the program had been delayed or postponed.

Barriers and facilitators for return to work and implementation of the program

The participating professionals often indicated that they did not know whether a certain factor had hampered or facilitated realization of RTW. However, the content of the program was mostly seen as facilitating. To illustrate, in most cases the insurance physician (75% of the cases), labor expert (93%), RTW coordinator (63%) and case manager (57%), indicated that the development of a RTW action plan had facilitated RTW. Of the participants 55%

indicated that this had facilitated RTW. Also many of them could not tell whether this had been facilitating. This was also true for the job search by the vocational rehabilitation agencies and by themselves.
Many times the insurance physician (43% of the cases), the labor expert (70%), the RTW coordinator (57%) and the case manager (76%) indicated that their time investment in the program had facilitated a successful execution of the program. This item was also often evaluated as "neutral".

Satisfaction and experiences

Integrated care

In more than half of the cases (53%) in which the insurance physicians reported that they had contacted the participant's healthcare provider(s), the insurance physicians evaluated the attitude of the healthcare provider as active and cooperative. Often they were also positive about the communication with the healthcare provider(s) (63% of the cases), and with the degree of agreement that had been reached (53%). Twenty-one participants reported that they had consulted the insurance physician. Of them about one-third had indicated that their insurance physician was sufficiently aware of the treatment by the general practitioner (GP) or psychologist. Also many of these items were evaluated as "neutral" or "not applicable".

Participatory approach

In many cases the labor expert was positive about the contribution of the participant to the identification of obstacles for RTW (96% of the cases), the development of solutions to overcome these obstacles (74%) and the discussion of suitable workplaces (78%). Often the labor expert also thought that the RTW coordinator had contributed largely to the identification of obstacles for RTW (93% of the cases), the development of solutions to overcome these obstacles (85%), and the discussion of suitable workplaces (82%). Moreover, the labor experts very frequently reported that the participant and the RTW coordinator had reached consensus about solutions (96% of the cases) and suitable work (93%). Twenty-three participants indicated that they had visited a labor expert, and the

majority (74%) reported that the labor expert had contributed largely to a sense of security or support and to the perceived equality between the participant and the RTW coordinator (78%).

Direct placement in a competitive job

The case managers of the vocational rehabilitation agencies were more often dissatisfied (24% of the cases) than satisfied (19% of the cases) with placement of the sick-listed worker in a suitable job. Also participants were more frequently dissatisfied (36% of the participants) than satisfied (10%) with the job offer by the vocational rehabilitation agency. The number of cases in which the RTW coordinator positively evaluated the offering of a suitable job by the agency was equal to the number of cases in which dissatisfaction was expressed (about 30% of the cases). In the remaining cases these items were evaluated as neutral or not applicable.

Satisfaction by participants

Table *A2* (Appendix) shows how the participants had evaluated the guidance of the OHC professionals who had participated in the participatory supportive RTW program. In Table *A3* (Appendix) is presented how the participants generally had appreciated the guidance by all professionals who had participated in the program. Overall, satisfaction was good. However, also many items were evaluated as “neutral” or “not applicable”.

Discussion

The aim of this study was to conduct a process evaluation of a participatory supportive RTW program for workers without a (permanent) employment contract who were sick-listed due to a CMD, alongside the Co-WORK study. The process evaluation revealed that only a small part of all intervention group participants had actually participated in the program. In these cases, the dosage of the program was high. However, the application of an integrated care approach had been reported in only half of the cases. Moreover, fidelity to the program was low to reasonable. This poor fidelity was mainly the result of a delay in the execution of the program and a low number of placements in a suitable competitive job.

Nevertheless, most of the stakeholders were satisfied with the use of the participatory approach, which was the core of the participatory supportive RTW program.

Comparison with other studies

Earlier studies have demonstrated good feasibility of similar participatory RTW programs for sick-listed employees with low back pain, employees with distress and sick-listed unemployed and temporary agency workers with musculoskeletal disorders [11-14]. Our process evaluation revealed that the execution of a participatory RTW program aimed at workers without a (permanent) employment contract who were sick-listed due to a CMD was less successful.

Although the program was aimed at a large group of sick-listed workers, in our trial the program seemed to be suitable for only a small group, ie, those whose sickness benefit was not likely to end in the near future and who had no contra-indication for participation in the program. The percentage of participants with a medical contra-indication in our study (28%) was much higher compared to the percentage in an earlier study by Van Beurden et al [13] on a similar participatory RTW program for sick-listed workers with musculoskeletal disorders, which was 13%. Compared to this study, we also found more delay in the execution of the program [13]. Both studies focused on workers who had filed a sickness benefit claim at the Dutch SSA because they had no employer, but for different health reasons. The high number of medical contra-indications and the delay in the execution of the program are possibly related to the type of health complaints of the sick-listed workers in our study, ie, mental health problems, and the assessment of these problems by the stakeholders. Another explanation for these differences could be that in the study by Van Beurden et al [13] the sick-listed workers were placed in a (therapeutic) workplace with ongoing benefits from the SSA, whereas in our study only direct placement in a competitive (paid) job was considered suitable [6].

To our knowledge, this was the first time that direct placement in a competitive job was added to a participatory approach in order to improve RTW of sick-listed workers. Unfortunately, only two sick-listed workers were actually placed in a suitable competitive job by the contracted vocational rehabilitation agencies. Although the support of the vocational rehabilitation agencies was possibly still ongoing at the time of the process

evaluation, the number of placements in a competitive job was very low. Moreover, very few sick-listed workers were satisfied with the support by these agencies. This could be a result of a lack of support, but also external factors could have played a role. In the Netherlands, between 2013 and 2014 there was an economic recession, and employment opportunities were limited [5,19]. This may explain why the case managers of the vocational rehabilitation agencies frequently reported difficulties in finding a suitable job.

Integrated care was another intervention component that was added to the original participatory RTW program. Despite the fact that this was part of the protocol, only in half of the cases the insurance physician reported that he/she had contacted the participants' healthcare provider(s). This is in line with an earlier study by Anema et al [20], reporting on the limited communication and collaboration between GP's and occupational physicians when providing OHC guidance for sick-listed employees.

Compliance to the main intervention component, the participatory approach, was also lower compared to the application of such an approach in earlier studies [11-14]. In many of the action plans, it was not explained how the identified obstacles interfered with RTW. Furthermore, the obstacles for RTW identified in our study mostly expressed feelings of uncertainty and mental health problems, while obstacles identified by sick-listed workers in previous studies were more frequently work-related, eg, obstacles related to job design and physical or mental workload [11-14]. An explanation for this discrepancy is that in our study almost all sick-listed workers were already unemployed before they became sick-listed.

Despite the often unclear descriptions of obstacles for RTW, most action plans did contain ≥1 practical solution to overcome these obstacles and clear descriptions or examples of suitable work were given. Moreover, in most cases both the participant and the professionals involved were positive about the way the RTW action plan had been developed, and they all thought this plan would facilitate RTW. The majority of the participants were also satisfied with the coordination by their labor expert, which is in accordance with the high satisfaction with process guidance found in the study of Van Beurden et al [13]. Possibly, the application of the participatory approach has had the intended function, although the execution of this component in practice – ie, its form – differed from the protocol. A distinction between form and function of an intervention has

been made earlier by Hawe et al [21]. They advocated a focus on the function of a complex intervention instead of its form, so that the complexity of this type of interventions could be taken into account [21].

Strengths and limitations

An important strength of this process evaluation is that all stakeholders were consulted. This made it possible to integrate experiences of stakeholders with various interests in the OHC field. Consequently, the evaluation of a process evaluation component was seldom based on perceptions of only one stakeholder.

Another strength of our study is that we used a well-known framework to structure our evaluation. The framework of Linnan and Steckler [7] helped us to identify, analyze and describe key process evaluation components.

In this evaluation we distinguished between the three basic components of the participatory supportive RTW program, ie, integrated care, a participatory approach and direct placement in a competitive job. This enabled us to differentiate between those components of the program that can successfully be implemented in daily practice and those components that still need some improvements. However, by making this distinction we ignored the fact that a complex intervention is more than only a sum of the parts [21]. Also the relations between the intervention components themselves and their relation with the intervention setting, may have affected the execution of the intervention. We did not take these interactions into account, which can be seen as a limitation of our study.

Because of the study design, we were not able to disentangle the reach of the participatory supportive RTW program from the study's reach, which is a second limitation of our study. Furthermore, it was not possible to determine whether those who did not respond to the invitation for the study would have been eligible to participate, as they were not screened. Possibly, they were not (all) belonging to the target population as was assumed in the calculation of the reach.

Also the recruitment procedures were related to the design of the RCT. Because allocation to the intervention program was based on randomization, it was important that the sick-listed worker was willing to participate in both the intervention and the control group. This

process evaluation does not reveal how sick-listed workers can be encouraged to participate in the intervention program.

Another limitation of our study is that mainly questionnaires were used for our data collection. This quantitative research method seemed insufficient to gather data about experiences and satisfaction with the program and about barriers and facilitators for realization of RTW and for implementation of the program in practice. Many of the items to measure these constructs were evaluated as "neutral" or "not applicable".

A last limitation of our study is that probably only sick-listed workers and professionals interested in the Co-WORK study, participated in the participatory supportive RTW program. This may have resulted in selection bias. For this reason, generalizing the results of this study to another context could be difficult.

Implications for practice and research

Despite the positive evaluation of the participatory approach, it is likely that the low compliance measured in this evaluation will affect the outcomes of our trial. The results of this process evaluation will assist us in the interpretation of the effectiveness evaluation of the participatory supportive RTW program. Nevertheless, new research questions have emerged. Further research could investigate the function of the participatory approach according to the stakeholders who participated in the program, perceived barriers for a successful application of integrated care and direct placement in a competitive job, reasons behind the high number of cases in which there was a contra-indication for participation in the program and reasons for delay in the execution of the program. In this way, more in-depth insight will be obtained about the execution of the full program in our trial. This will be helpful in both the interpretation of the trial results and the decision for future implementation of the program. The use of qualitative research methods seem to be most appropriate to address these topics for further research and to unravel processes of implementation and change [22].

Appendix

Table A1 Fidelity scoring system

Steps	Fidelity score
Step 1 and 2. *Consult with RTW coordinator & consult insurance physician (usual care)*	1
Consult insurance physician took place >2 weeks after allocation to intervention team	- 1
Insurance physician contacted healthcare provider(s) of participant	2
Insurance physician contacted healthcare provider(s) not by telephone	- 1
Step 3. *Inventory of obstacles for RTW*	2
Only the participant and the labor expert had a meeting	- 1
Only the RTW coordinator and the labor expert had a meeting	- 1
Step 4. *Brainstorm session*	2
Brainstorm session took place >2 weeks after meeting insurance physician	- 1
Action plan for RTW was written	2
Step 5. *Sick-listed worker was referred to vocational rehabilitation agency*	2
Contracting agency took place >1 week after brainstorm session	- 1
Step 6. *Vocational rehabilitation agency offered two suitable jobs*	2
First job offer was >4 weeks after contracting agency	- 1
Placement in a suitable job by vocational rehabilitation agency	2
Maximum total score:	15

Table A2 Participants' evaluation of guidance by OHC professionals participating in intervention

		N=31
*Since you became sick-listed, have you seen the **insurance physician** of the SSA?*	*Yes*	*21 (68%)*
The insurance physician…	(totally) agree	
properly understood my health problems		19 (91%)
properly understood my problems with work resumption		17 (81%)
treated me nicely		19 (91%)
knew what he/she was talking about		19 (91%)
gave me good advice about my health		16 (76%)
treated my complaints confidentially		17 (81%)
*Since you became sick-listed, have you seen the **labor expert** of the SSA?*	*Yes*	*23 (74%)*
The labor expert…	(totally) agree	
properly understood my problems		20 (87%)
treated me nicely		23 (100%)
knew what he/she was talking about		23 (100%)
gave me good advice about my RTW possibilities		16 (70%)
seemed knowledgeable		22 (96%)
*Since you became sick-listed, have you seen the **RTW coordinator** of the SSA?*	*Yes*	*23 (74%)*
The RTW coordinator…	(totally) agree	
properly understood my problems		17 (74%)
treated me nicely		20 (87%)
knew what he/she was talking about		20 (87%)
gave me good advice about my RTW possibilities		12 (52%)
seemed knowledgeable		18 (78%)

Table A3 Participants' general satisfaction with guidance by OHC professionals participating in intervention

		N=31
To what extent are you satisfied with the guidance by the *insurance physician*	(Very) satisfied	16 (52%)
	(Very) dissatisfied	5 (16%)
	Neutral/NA	10 (32%)
To what extent are you satisfied with the guidance by the *labor expert*	(Very) satisfied	17(55%)
	(Very) dissatisfied	3 (10%)
	Neutral/NA	11 (36%)
To what extent are you satisfied with the guidance by the *RTW coordinator*	(Very) satisfied	15 (48%)
	(Very) dissatisfied	5 (16%)
	Neutral/NA	11 (36%)
To what extent are you satisfied with the guidance by the *case manager of the vocational rehabilitation agency*	(Very) satisfied	10 (32%)
	(Very) dissatisfied	5 (16%)
	Neutral/NA	16 (52%)

NA=Not applicable

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5

Execution of a Participatory Supportive Return to Work Program within the Dutch Social Security Sector: a Qualitative Evaluation of Stakeholders' Perceptions

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Abstract

Background A process evaluation of a participatory supportive return to work (RTW) program, aimed at workers without a (permanent) employment contract who are sick-listed due to a common mental disorder revealed that this program was executed less successfully than similar programs evaluated in earlier studies. The program consisted of a participatory approach, integrated care and direct placement in competitive employment. Aim of this study was to get a better understanding of the execution of the program by evaluating stakeholders' perceptions. In the absence of an employer, the program was applied by the Dutch Social Security Agency (SSA), in collaboration with vocational rehabilitation agencies. Together with the sick-listed workers, these were the main stakeholders. Our research questions involved stakeholders' perceptions of the function(s) of the program, and their perceptions of barriers and facilitators for a successful execution of the program within the Dutch social security sector.

Methods Semi-structured interviews were held with five sick-listed workers, eight professionals of the SSA and two case managers of vocational rehabilitation agencies. Interview topics were related to experiences with different components of the program. Selection of respondents was based on purposive sampling and continued until data saturation was reached. Content analysis was applied to identify patterns in the data. Two researchers developed a coding system, based on predefined topics and themes emerging from the data.

Results Although perceived functions of some components of the program were as intended, all stakeholders stressed that the program often had not resulted in RTW. Perceived barriers for a successful execution were related to a poor collaboration between the Dutch SSA, vocational rehabilitation agencies and healthcare providers, the type of experienced (health) problems, time constraints, and limited job opportunities.

Conclusions For future implementation of the program, it will be important to consider how a better integration of services by the Dutch SSA, vocational rehabilitation agencies and the mental healthcare sector can be improved in order to address treatment and vocational needs simultaneously, and to better match the sick-listed worker with the limited opportunities in the Dutch labor market. (Trial registration NTR3563)

Background

Complex interventions consist of multiple interacting components [1,2]. When studying its effectiveness in a randomized controlled trial (RCT), it is often difficult to determine which components have caused an effect. Insight into the execution of these components in the study's practice helps to interpret the results of a RCT [2,3], and to improve the feasibility of the intervention for future implementation [2]. Therefore, process evaluations alongside RCTs have become more common [4].

In an earlier study we conducted a process evaluation of a participatory supportive return to work (RTW) program, alongside a RCT, using quantitative research methods [5]. Aim of the participatory supportive RTW program was to improve RTW of workers without a (permanent) employment contract, sick-listed due to a common mental disorder (CMD). These workers often face a greater distance to the labor market compared to sick-listed permanent employees, as many of them have no workplace to return to [6]. The program was evaluated within the Dutch social security sector. In the Netherlands, sick-listed workers who have no (longer an) employer are entitled to occupational healthcare (OHC) by the Dutch Social Security Agency (SSA). The core of the program consisted of a participatory approach in which the sick-listed worker was encouraged to identify obstacles for RTW and to think of solutions and suitable work, in cooperation with a RTW coordinator of the Dutch SSA. This was monitored by a labor expert, whose responsibility it was to reach consensus between the sick-listed worker and the RTW coordinator and to summarize the proposed solutions and suggestions for suitable work in a RTW action plan. In order to agree on RTW possibilities and to avoid conflicting advice to the sick-listed worker, the insurance physician of the SSA applied an integrated care approach by contacting the healthcare provider(s) of the sick-listed worker directly after the medical assessment. Vocational rehabilitation agencies were contracted in order to place the sick-listed worker in a suitable competitive job, based on the RTW action plan.

Findings of our process evaluation revealed that the participatory supportive RTW program was executed less successfully compared to similar programs evaluated in earlier studies [5]. A small part of the intervention participants actually started with the program. In many other cases the insurance physician assessed a contra-indication for participation in the

program. In these cases, the program was not considered suitable. Only for half of the sick-listed workers that actually followed the program, application of an integrated care approach was reported, and only two sick-listed workers were placed in a suitable competitive job. Often the program was not executed in accordance with the prescribed time-table. Nevertheless, overall satisfaction with the participatory approach was good [5].

The aim of this present study was to get a better understanding of the execution of the participatory supportive RTW program, by evaluating the execution of the intervention in relation to its setting. Several authors state that to account for the complexity of an intervention, it is not only important to quantify what happened in practice, but also to identify (contextual) factors that could have influenced the execution of an intervention [7-10], and to better understand the function of an intervention within its setting [11]. To illustrate, cultural expectations stemming from the beliefs, attitudes and experiences of stakeholders [7], staffing issues, such as time and resource difficulties or competing priorities, and organizational changes [8] are all factors that could influence the execution of an intervention. Vice versa, the very fact that the intervention is being conducted in a particular setting, could also change that setting. Often it is difficult to disentangle the intervention from its setting [10] and it may even be undesirable to do so. Hawe et al [11] explain that a complex intervention could look different across different settings, but could still have the same function(s). This means that when evaluating the execution of a complex intervention the question should be whether the intervention and its separate components have had the intended function rather than only how the intervention looked like in practice. In this study we evaluated the function(s) of the participatory supportive RTW program within the Dutch social security sector and we investigated barriers and facilitators for a successful execution of the program.

Qualitative study methods are considered useful for unravelling processes of change, exploring responses to the intervention and describing the intervention as executed in practice [12]. For that reason, we decided to conduct interviews with the main stakeholders of the participatory supportive RTW program, ie, sick-listed workers, professionals of the Dutch SSA and professionals of contracted vocational rehabilitation agencies. These stakeholder groups all represent different interests in the OHC field. Also their perceptions of RTW interventions are likely to differ, as can be illustrated by the studies of Tiedtke et al

[13] and Maiwald el al [14]. To be able to reflect on (the influence of) different perspectives of the participatory supportive RTW program and to get a broad understanding of the execution of the program, members of all main stakeholder groups were involved in our evaluation. Our main research questions were: what were stakeholders' perceptions of the function(s) of the participatory supportive RTW program? And what were their perceptions of barriers and facilitators for a successful execution of the program within the Dutch social security sector?

Methods

Design

The study design consisted of a qualitative study that was conducted alongside a RCT, titled "the Co-WORK study". The aim of the Co-WORK study was to investigate the (cost-)effectiveness of the participatory supportive RTW program in comparison with usual OHC by the Dutch SSA. The Medical Ethics Committee of the VU University Medical Center (Amsterdam, The Netherlands) gave Ethical approval for the study. The same committee declared that no comprehensive ethical review was needed for this qualitative study. The trial was registered at the Dutch Trial Register ("Nederlands Trial Register") on August 7, 2012 (NTR3563). All participants signed informed consent. More information about the trial can be found in the study protocol [15].

Study setting

The participatory supportive RTW program was aimed at unemployed workers, temporary agency workers and fixed-term contract workers who had filed a sickness benefit claim at the Dutch SSA, with mental health problems as main reason for their sickness benefit claim. Other stakeholders in the intervention were insurance physicians, labor experts and RTW coordinators of the Dutch SSA, and case managers of contracted vocational rehabilitation agencies. Seven SSA front offices participated in the program, located in the western, central and eastern region of the Netherlands, and three vocational rehabilitation agencies, operating on a national level.

Selection and recruitment of respondents

To get a broad understanding of perceived functions of the program and perceived barriers and facilitators for a successful execution, we wanted to identify all different perceptions of stakeholders in our study. We used purposive sampling to select stakeholders with various characteristics, as we expected that their perceptions of the execution of the program could differ. In the remaining of this article sick-listed workers who participated in the participatory supportive RTW program are referred to as "clients", as at least some of them were no longer sick-listed at the timing of the interviews.

Clients were selected on the basis of a variation in gender, educational level, age, duration of last employment, region and date of enrolment in the Co-WORK study. This information was collected during the baseline measurement of the Co-WORK study. Clients were matched to a SSA front office for RTW guidance, based on their zip code. By selecting clients from different regions they automatically belonged to different SSA front offices. We only selected clients that had actually participated in the participatory supportive RTW program. We also selected insurance physicians, labor experts and RTW coordinators from different participating SSA front offices. Moreover, these professionals had to have applied the participatory supportive RTW program at least twice, so that perceptions were not based on only a single case. As at each SSA office ≤2 professionals of each profession participated in the program, further selection based on other characteristics was not possible. This was also the case for the vocational rehabilitation agencies. Of the three participating agencies, one case manager was selected for an interview.

For the recruitment of respondents we used communication methods that had been used before for contacting the different stakeholders during the Co-WORK study. Clients were invited for an interview by telephone. During this telephone conversation, they were informed about the purpose of the interviews, the content and duration of the interviews, and other study procedures. In case someone was willing to participate, an appointment for an interview was made directly. A confirmation of this appointment was sent to the client by postal mail, including a summary of the study procedures and an informed consent form. By signing informed consent, the client agreed with his participation in the study and with the recording of the interview. Professionals were invited for participation by e-mail. In this

e-mail all study procedures were explained. By responding to the e-mail and expressing their willingness to participate, professionals consented to their participation in the study. Three clients that were approached for participation in an interview declined. Further, one insurance physician and one case manager did not respond to the invitation. Selection and recruitment of respondents for the interviews was continued, until data saturation was reached. Data saturation was considered to be reached when a new interviewee within a stakeholder group described to a large extent the same functions of the participatory supportive RTW program and/or the same barriers and facilitators for a successful execution of the program, compared to earlier interviewees within the same stakeholder group.

Study population

In total, 15 respondents were included in this study. Interviews were held with two insurance physicians, three labor experts, three RTW coordinators, two case managers of vocational rehabilitation agencies and five clients. Professionals were from four different SSA front offices and two vocational rehabilitation agencies. Clients belonged to four different SSA front offices. More background information on the clients can be found in Table 1.

Table 1 Background information clients [a]

	Gender	Age [a]	Education [ab]	Duration of last employment (years) [a]	Time between start in Co-WORK and interview (months)
Client 1	Female	55	High	3	13
Client 2	Male	54	Low	13	24
Client 3	Male	43	Low	0.5	18
Client 4	Female	43	Middle	6	12
Client 5	Female	29	Middle	0.7	17

[a] Measured at baseline of the Co-WORK study

[b] Low educational level included no education, primary school or lower vocational education; middle educational level included intermediate vocational education or secondary school; high educational level included higher vocational education or university

Interviews

The interviews were conducted by telephone by L.L., the first author of this study. The semi-structured interviews took 20–45 minutes, dependent on the number of topics discussed. Prior to the interviews a topic-list was created for each group of respondents or

stakeholders. This topic list contained both general topics and more specific questions about experiences with different components of the participatory supportive RTW program. Examples of general topics were ideas about the program's effectiveness and points of improvement. The more specific topics were related to the specific role of the respondent in the program, and differed between stakeholders. Insurance physicians were asked about contra-indications for participation in the program and about their experiences with the application of an integrated care approach. Labor experts and RTW coordinators were asked to evaluate the use of a participatory approach. Specific topics for the case managers of the contracted vocational rehabilitation agencies included ways in which was searched for suitable competitive jobs and their effectiveness. Clients were asked to evaluate all different components of the program, ie, integrated care, a participatory approach and direct placement in a competitive job. Table *A1* (Appendix) gives an overview of the topics that were discussed during the interviews. Each interview was recorded and fully transcribed (verbatim).

Analysis

Interviews were analyzed according to the main principles of content analysis. This means that the interview transcripts were analyzed through a systematic classification process of coding and identifying themes or patterns in order to describe the execution of the RTW program in practice [16]. Our aim was to identify perceived functions of the program and its separate components, and perceived barriers and facilitators for a successful execution. We wanted to get new insights and to relate this to existing knowledge. To reach these purposes, we used techniques from both directed and conventional content analysis. Initial codes were directed by the topic list, conform the principles of directed content analysis. Sub codes emerged from the data and were used to express meanings or themes, as is common in conventional content analysis [16]. Methods used for conventional content analysis are similar to the grounded theory (GT) approach, although the GT approach goes beyond content analysis to develop theory [16]. The analysis was done in multiple phases, consisting of open coding, axial coding and selective coding, based on the GT approach [17].

Two researchers performed the analysis. First, a list of initial codes was created by LL. Then, six transcripts were coded by LL and a research assistant, JO, independently, with the use of ATLAS.ti 7.1.8. During this phase of open coding, the transcripts were carefully read and divided into text parts. Text parts that seemed relevant, were coded by using the initial codes and creating (sub) codes. In this way, both researchers created an extended code list. During the phase of axial coding, the code lists were discussed by both researchers in order to reach consensus about a provisional list of codes and the interpretation of these codes. During this consensus meeting, it was carefully assessed whether the created codes were appropriate to describe the data and whether the text parts were given the most suitable code. The relation between main and sub codes was discussed, codes describing the same themes were clustered, and codes describing multiple themes were split into different codes. After consensus was reached, all transcripts were (again) analyzed by L.L, using the provisional code list. When necessary, new codes were created. Finally, patterns in the data were identified by looking for returning themes and by making connections between these themes. During this phase, we identified perceived functions of the participatory supportive RTW program and of its separate components, and perceived barriers and facilitators for a successful execution of the program. Codes describing the functions of the program were mostly directed by the predefined topic list. Barriers and facilitators mostly emerged from the data. All authors were involved in this phase of selective coding.

We used quotes originating from the interviews to illustrate our findings. Cited professionals were described by the job title of their profession. For clients, we used numbers (1–5), corresponding to the numbers used in Table 1. Numbers were also used to differentiate between ≥2 respondents with the same profession, when multiple quotes were used to illustrate one particular finding.

Results

We present stakeholders' perceptions of 1. functions of the participatory supportive RTW program, 2. barriers for a successful execution of the program, and 3. facilitators for a successful execution of the program. We distinguished between perceived functions of the program's separate components, ie, integrated care, a participatory approach and direct

placement in a competitive job. Subsequently, frequently mentioned barriers and facilitators for a successful execution of the program were summarized. We distinguished between perceptions by different stakeholders, when they had different points of view.

Perceived functions of the participatory supportive RTW program

Perceived functions of integrated care

The insurance physicians thought that the communication and cooperation between them and the clients' healthcare provider(s) had improved after they had contacted the healthcare provider(s).

> *Insurance physician 1: "I believe that working together for a client can have a positive effect, because it leads to respect for each other's discipline."*
>
> *Insurance physician 2: "It leads to interaction, while normally you ask for information and that's it."*

Another perceived function of this component of the participatory supportive RTW program was a shift in paradigm by the healthcare providers from a disability-oriented approach to an approach in which work became more central.

> *Insurance physician: "My experiences were positive, because the healthcare providers became aware of the clients' participation in the program and also responded positive to the focus on work resumption. So, this had opened the healthcare providers' eyes and they were no longer solely focused on the health complaints of their clients."*

However, the insurance physicians not always thought it was necessary to contact the clients' healthcare provider(s). One of the insurance physicians stressed that only sick-listed workers with mild (mental health) problems participated in the participatory supportive RTW program. Therefore, no conflicting advice could be expected. In case of more severe problems, the insurance physician would not have the client start with the program.

The clients indicated that work resumption was barely discussed with their healthcare providers. They also had not received any conflicting advice from their healthcare providers regarding their possibilities for RTW.

> *Client 4: "Of course he understood my situation. He told me: 'You're not fit. You're not at your best. You should realize that your chances of getting hired are extremely small.'."*

Perceived functions of a participatory approach

The RTW coordinators and labor experts thought that it was important to actively involve the client in the creation of a RTW action plan and also believed that this participatory approach had actually led to a more active participation in vocational rehabilitation by the client.

> *Labor expert:* "*Normally we ask clients about their background and we discuss some obstacles, but then we mainly speak about limitations that were noticed by the physician. Now, clients had to come up with their own ideas about obstacles and suggestions to overcome these obstacles. This self-reflection was hard, but it helped to get them in another mindset."*

According to the labor experts and RTW coordinators, many clients were strongly involved in the identification of obstacles and finding solutions and suitable work. However, they also though that the input of the clients varied.

Another function of the participatory approach, perceived by these stakeholders, was that it had helped clients to get a better understanding of their barriers and possibilities for RTW.

> *Labor expert: "I found it very surprising how clients already had made some important steps in the time between the meeting I had with them for the identification of RTW obstacles and subsequently the brainstorm session in which they discussed solutions to overcome these obstacles with the RTW coordinator, because it was clear for them what was the core of their problems and which of their problems they could influence."*

The clients did not mention these functions when they reflected on the counselling they had received by the SSA. From their perception, obstacles for RTW and solutions to overcome these obstacles had barely been discussed. They thought that they had received not enough counselling by the SSA, as was explained by one of the clients:

> *Client 2: "They assessed my capabilities and such. They also contacted the vocational rehabilitation agency. Then that part of the program started. And if*

there were any questions, I could contact them. But these did not really occur. We simply proceeded with the program and I did not receive any further support."

Perceived functions of direct placement in a competitive job

All clients indicated that their participation in the participatory supportive RTW program did not result in RTW in a competitive job. Also the other stakeholders confirmed that the program in many cases did not have the intended result, as many of their clients were not placed in competitive employment.

When the case managers of the vocational rehabilitation agencies were asked what actually had been done after referral of the client to their agency, they explained that they had put in a lot of effort to place the clients in a suitable job. They stressed that they did more than solely job hunting, eg, helping the client with the writing of their CV and preparation for a job interview.

When describing the support they had received from the vocational rehabilitation agencies, some clients told that the case manager had not taken their job preferences into account and they had been treated like numbers. Others indicated that they had been in regular contact with the case manager who had helped them with their CV and application letters. Some mentioned that the case manager also had contacted companies to look for job opportunities. As a result, some clients were more positive than others. Still, most of them emphasized that they had received too little support from the case managers.

Client 1: "I had one meeting with her and she would set to work. Finally she called me and said: 'I never hear anything from you'. I asked her: 'But shouldn't I hear something from you?' Actually, I did not understand anything of it."

The RTW coordinators of the SSA were responsible for monitoring the implementation of the RTW action plan. They also thought that the quality of the contracted vocational rehabilitation agencies differed a lot. They were dissatisfied with one agency, because of poor communication and involvement of this agency, but satisfied with another agency, because this agency started their job search very early after referral of a new client to their agency.

When clients were asked about their own participation in the program, they often indicated that they had been looking for job opportunities by themselves and had applied for several vacancies. They all wished to return to work. Some had found a voluntary job.
The case managers were quite positive about the cooperation by the clients in the search for a suitable job. However, in some cases they thought that the client could have participated more actively.

Perceived barriers for a successful execution of the participatory supportive RTW program

Poor collaboration between the Dutch SSA, the vocational rehabilitation agencies and the (mental) healthcare sector

The professionals of the SSA mentioned several barriers that were related to a poor collaboration between their service and the contracted vocational rehabilitation agencies and/or the mental healthcare sector.
One of the insurance physicians explained that, because of segregation of services by the SSA and the healthcare sector, it was sometimes difficult to get in touch with the clients' healthcare providers.

> *Insurance physician: "That could be very time consuming. Some of the healthcare providers I could not reach by telephone. I even did not get their numbers. Once, the assistant of a general practitioner did not want to give me the number of a healthcare provider, because she was not sure that I was who I said that I was."*

Another example of a poor collaboration mentioned by the SSA professionals was that the vocational rehabilitation agencies often analyzed obstacles and solutions for RTW, while this was already done by the SSA. During the application of a participatory approach at the SSA, an action plan for RTW was made. From the perspective of the SSA professionals, the RTW action plans were useful in the search for a competitive job, as these summarized the most important obstacles for RTW, preconditions for RTW and suitable work. However, they thought that the agencies made only little use of the information in these action plans. This was confirmed by the case manager of one of the contracted vocational rehabilitation agencies, who explained that it could sometimes be necessary to use a broader perspective:

> *Case manager of a vocational rehabilitation agency: "We talked with our client about what was discussed with the SSA, to see if this was still applicable. That was often the case. Sometimes we also considered other possibilities than the ones discussed by the SSA, so that we could use a broader perspective for our search. This was sometimes necessary, because we had to take the limited opportunities in the labor market into account."*

The RTW coordinators of the SSA also admitted that, mainly due to time constraints, after referral of the client to the vocational rehabilitation agency they often had only limited contact with the client and barely monitored the actual implementation of the RTW action plans.

Type of (health) complaints

According to all stakeholders the type of (health) complaints experienced by the clients sometimes hampered a successful execution of the participatory supportive RTW program. In other words, the participatory supportive RTW program was not always considered suitable. In case the program was not seen as appropriate, this was often related to the perceived severity of the client's (mental health) problems.

The insurance physicians indicated that for clients with severe (mental) health problems, participation in the program early after sick-listing could be too demanding, because of its intensity and early focus on work, and they were afraid that it would worsen their complaints.

> *Insurance physician: "Often it concerned more complex cases, clients who needed attention on multiple aspects to improve functioning. In those cases, the program would have counteracted its purpose, because having to visit different professionals who ask different things would have been too demanding and intensive. It seems easy, but for some this is a huge task."*

One of the RTW coordinators emphasized that for clients who participated in the participatory supportive RTW program it could be very difficult to point out obstacles for RTW, as a consequence of their mental health problems:

> *RTW coordinator:* *"I believe that when you have serious mental health complaints, you can't think clearly anymore. You don't know exactly what has caused your complaints and what your capabilities are."*

Mentioned by both labor experts and RTW coordinators was the difficulty to come up with solutions for obstacles for RTW, when these obstacles were related to the experienced mental health problems.

> *Labor expert:* *"When someone has psychological problems it is more difficult to find a solution, then when someone faces a more concrete RTW obstacle"*

Also the placement in a competitive job was according to many stakeholders sometimes hampered by characteristics of the clients, such as an older age, a large distance to the labor market, a lack of application skills, passivity and mental health problems. According to some, this could lead to feelings of uncertainty, which formed another major obstacle for RTW.

> *Client 4:* *"You have to compete with the rest of the world, while your own perception is that you're not capable enough. That's like being placed inside a boxing ring, together with professional boxers, while you're still nothing."*
>
> *Case manager of a vocational rehabilitation agency:* *"…not searching for vacancies, because they were so insecure about their own capabilities that it complicated their job search. Every time they asked themselves: 'Am I capable enough?'."*

One of the case managers believed that the presence of mental health problems sometimes resulted in passivity and a lack of motivation. According to this case manager some clients also placed great demands on a vacancy, which made it difficult to find a suitable job.

Some of the professionals doubted if the client was ready to return to work, given his or her mental health problems. They thought that these clients needed more training prior to placement in a competitive job, such as training in empowerment or application skills, to increase their confidence, skills and motivation.

> *RTW coordinator:* *"To be able to return to work, sometimes an increase of their mental resilience was necessary."*

Time constraints

All stakeholders indicated that a lack of time was an important barrier for a successful execution of the program.

The labor experts and RTW coordinators stressed that the application of a participatory approach was very intensive. On the one hand this gave them the opportunity to get a full understanding of the client at an early stage and to gain the client's confidence in their counselling. On the other hand, it was time consuming and asked a lot from both professionals and clients.

An important obstacle mentioned by all stakeholders was a lack of capacity at the SSA or vocational rehabilitation agency, often resulting in limited time to execute the program.

> *RTW coordinator: "The workload at our department was high and we had to achieve several targets. Because there were no performance indicators for our participation in the Co-WORK study, often this work was done after other work was finished."*

As was illustrated in this last quote, the limited capacity was partly related to the study setting. The participatory supportive RTW program was not part of the daily practice of the professionals and there were often other competing priorities. Moreover, only a few professionals in the organizations were trained in the program. In this way, it was not always possible to schedule all steps of the program in accordance with the prescribed time frame, as was explained by one of the labor experts:

> *Labor expert: "In this way, every team member has to be available all the time. The workload was very high."*

The case managers found that the period of 2–3 months in which they had to place the client in a suitable competitive job was too short, especially when the client was still facing mental health problems.

> *Case manager of a vocational rehabilitation agency: "Given the problems of some people, or actually the majority of the people, a time-frame of 2–3 months appeared to be rather short sometimes. You want to get someone back on track very quickly, while sometimes there are serious complaints that get in the way and that need more attention."*

Also many clients stressed that the received support for their job search was too short in time.

Limited labor market opportunities

A frequently mentioned barrier was the limited availability of suitable paid jobs in the Dutch labor market during the execution of the program, caused by the economic recession at the time.

The labor experts and RTW coordinators thought that in this situation it was difficult to think of suitable work. A RTW coordinator explained that it was often difficult to convert the preconditions for RTW into a concrete job:

> *RTW coordinator: "You can wish to work on your own, because you can't work together, or to get only one task at a time, or to have a break every ten minutes. Then you have figured out how you could function, but when you present these wishes to an employer, it is not realistic to think that they will offer you a job. Sometimes these work solutions may have been helpful, but they were not realistic to present to an employer."*

Many stakeholders acknowledged that the clients often had to compete with a large number of other job seekers and many of them believed that an employer was not willing to hire an employee who is not fully employable.

Perceived facilitators for a successful execution of the participatory supportive RTW program

Diminishing capacity needed

A facilitating factor mentioned by the labor experts was diminishing the number of professionals involved in the program, for example by letting the RTW coordinator perform all steps of the participatory approach. According to them, in this ways the capacity problem could be tackled.

One of the RTW coordinators and one of the case managers thought that involvement of the vocational rehabilitation agency in the development of the RTW action plan could have facilitated the search for a suitable job. Because of their knowledge of the labor market, the

case managers could have helped matching the clients' wishes and preconditions for RTW with opportunities in the labor market.

Creating opportunities in the labor market

Some clients, and also a few professionals, indicated that it would also have helped if the vocational rehabilitation agencies had already made some work arrangements with employers, including arrangements regarding therapeutic or sheltered workplaces. They stressed the importance of work and also of voluntary work, which could serve as a stepping-stone to more sustainable employment and help clients to become more self-confident.

Discussion

Main findings

The aim of this study was to gain insight into the execution of the participatory supportive RTW program within the Dutch social security sector, by evaluating stakeholders' perceptions of the function(s) of the program, and their perceptions of barriers and facilitators for a successful execution. The findings of our study reveal that according to the professionals of the Dutch SSA, the functions of two components of this program – integrated care and a participatory approach – were as intended. These functions were respectively improving the communication and cooperation with the clients' healthcare provider(s) to avoid conflicting advice about the clients' possibilities for RTW, and making a consensus-based RTW action plan. However, the clients did not mention these functions. Instead, most of them stressed that they had received too little support from the SSA. Furthermore, both professionals and clients indicated that the job search based on the RTW action plan often did not result in placement of the client in a suitable competitive job. The execution of the program in the study's practice appeared to be often not proceeded as intended. Several barriers for a successful execution of the full program were mentioned by the stakeholders. These barriers were related to a poor collaboration between the SSA, the vocational rehabilitation agencies and the mental healthcare sector, the type of (health) problems experienced by the clients, time constraints for the professionals, and limited

opportunities in the Dutch labor market. Perceived facilitators for a successful execution of the program were: diminishing the number of SSA professionals involved, earlier involvement of the vocational rehabilitation agency, and making work arrangements with employers.

Interpretation of findings

The use of a participatory approach had been positively evaluated in the previous process evaluation [5]. This could be explained by the perceived function of this component according to the professionals who applied this approach, which was in accordance with the intervention protocol. The perceived barriers for a successful execution of the full participatory supportive RTW program may help to explain the low number of sick-listed workers that was considered suitable for participation in the program and the overall low adherence to the protocol [5].

An important barrier, mentioned by many stakeholders, was the limited availability of suitable jobs in the labor market. This barrier was seen before in studies evaluating the feasibility and effectiveness of supported employment in the Netherlands and other European countries [18,19]. Related to this barrier was the reluctance of Dutch employers to hire an employee with (mental) health problems, as perceived by some of the stakeholders. The same barrier was identified in the study of Van Erp et al [19], who explained that because of a high level of employment protection in the Netherlands, hiring a worker with health problems implies a risk for the employer. Respondents in our study assumed that employers would not take this risk when there were also other candidates without health complaints.

The perceived barriers related to the type of (health) complaints, illustrate that there is still a very cautious approach regarding an early RTW of persons with a CMD. Although "place-and-train" interventions such as supported employment have received growing attention in the last few years [18-20], in Europe the most common approach is still to "train-and-place" in (sheltered or volunteer) work, with the emphasis on prevocational training [18,19]. This may explain why stakeholders of the participatory supportive RTW program stuck to this approach.

The difficulties in the collaboration between the SSA, vocational rehabilitation agencies and the mental healthcare sector mentioned by professionals in our study illustrate how, despite attempts made for a better integration, this remained limited. This limited integration of services can be explained by comparing the participatory supportive RTW program with other RTW interventions. When we look at RTW interventions in which an integrated care approach was applied successfully [18,20,21], we see an early involvement of vocational services, and an integration of healthcare services and vocational services in one team of professionals. In the participatory supportive RTW program, the making of a RTW action plan, coordinated by the SSA, and placement in a suitable job, executed by vocational rehabilitation agencies, were organized as consecutive instead of integrated steps. Moreover the organization of (mental) health services and vocational services remained parallel.

The different perceptions of functions of the participatory supportive RTW program by clients and professionals of the SSA was in line with previous research. The study of Maiwald et al [14] revealed that clients and professionals perceived the effectiveness of a RTW intervention differently because they focused on different outcomes. The clients who were interviewed in our study stressed that they wished to return to work. However, their participation in the program had not resulted in RTW in a competitive job. This might explain why according to them, the program did not have the intended function. The professionals of the SSA seemed to focus also on other outcomes, such as and active participation of the sick-listed worker. This might explain their more positive evaluation.

Strengths and limitations of this study

An important strength of this study is that members of all stakeholder groups were interviewed. This made it possible to look for differences and similarities between perceptions of these different stakeholders of the execution of the participatory supportive RTW program in practice. This helped to get a full understanding of functions of the program according to these different stakeholders, and their perceptions of barriers and facilitators for a successful execution.

Another strength of this study is that the coding system was developed by two researchers, which increases the credibility of the analysis. However, the co-authors of this paper were

only involved in the last phase of coding, ie, selective coding. This can be seen as an important limitation of this study.

Another limitation of this study was that all interviews were held by telephone. This method was chosen, because we expected that both clients and professionals were more eager to participate and to talk freely when they could participate via a telephone conversation. However, non-verbal communication was not visible for both the interviewer and the interviewee, which is an important limitation of this method.

The non-response among some clients could be seen as another limitation. This could have biased our findings, as clients that agreed to participate might differ in perceptions from the ones who did not agree. However, the application of purposive sampling helped us to include clients with various characteristics.

Non-response among professionals was low. Nevertheless, input of one contracted vocational rehabilitation agency was missing, as its case manager was no longer working for this agency and we were not able to contact him. Furthermore, professionals of only four SSA offices participated in the present study, whereas in total seven SSA offices had participated in the Co-WORK study. This was caused by the very low number of cases in which the participatory supportive RTW program had been applied at the remaining offices. By selecting professionals that applied the program at least twice, we may have selected professionals who were more willing to implement the program. Still, also the selected professionals had applied the program only a few times. The number of clients that had actually participated in the intervention was very low (N=36) [5]. This means that the number of cases per professional in which the program was applied was also low. Both the applied selection of professionals, and the low number of cases per professional could have biased our findings and can be considered as important limitations of this study.

The timing of the interviews can be seen as another cause of possible bias and forms another limitation of this study. All clients had started with the program >1 year before the interview. This might have resulted in recall bias.

Implications for practice and research

Our findings emphasize the need for a better integration of services from the Dutch SSA, vocational rehabilitation agencies and from the mental healthcare sector, in order to respond

to the (vocational) needs of workers without a (permanent) employment contract, sick-listed due to a CMD. An important point of improvement mentioned by the respondents in this study is an earlier involvement of vocational rehabilitation agencies in RTW counselling.

Furthermore, lessons may be learned from supported employment [22]. In this evidence-based approach employment specialists and healthcare providers cooperate in order to search for a suitable job as quickly as possible, and to support their client during work resumption for as long as needed. Until now, the focus of studies evaluating this practice has been almost exclusively on people with severe mental illnesses [22]. It seems worthwhile to investigate whether a similar collaboration is effective in improving RTW for people with less severe and more common mental health problems, by simultaneously addressing treatment and vocational needs.

To stimulate a successful integration of mental healthcare in vocational rehabilitation of workers without a (permanent) employment contract who are sick-listed due to a CMD, it seems important that employment problems and outcomes become central in the treatment of mental health problems [22]. In this regard, the recently signed covenant between the Dutch SSA and mental healthcare sector could be seen as an important step forward. Possibly, this covenant could be taken as a starting point to stimulate further integration of services.

We recommend to evaluate in future research whether more intensive and earlier involvement of vocational rehabilitation agencies and mental healthcare providers would help to identify barriers for RTW in an early phase, and to better match the sick-listed worker with (the limited) opportunities in the labor market.

Conclusions

The results of this study indicate that, despite the quite positive evaluation of the functions of integrated care and a participatory approach, there were multiple barriers for a successful execution of the full participatory supportive RTW program. Execution of the program seemed to be highly influenced by the limited availability of suitable jobs in the Dutch labor market, the belief of some professionals that an early RTW of sick-listed workers

with mental health problems should be avoided, the segregation of services within the Dutch social security sector, and by time constraints for professionals. For future implementation of the program in the Dutch social security sector, it will be important to consider how integration of services by the Dutch SSA, vocational rehabilitation agencies and the mental healthcare sector can be improved in order to respond to the (vocational) needs of sick-listed workers with a CMD.

Appendix

Table A1 Topic-list

Topics	Discussed with
General	
Experience with participation in the intervention	All respondents
Satisfaction with intervention	All respondents
Ideas about an early RTW of sick-listed workers with a CMD	All respondents
Effectiveness of intervention	All respondents
Points of improvement of intervention	All respondents
Relationship between intervention and expectancies beforehand	Clients
Relationship between intervention and needs for RTW guidance	Clients
Own role in conduct of intervention	Professionals
Integrated care	
Experience with guidance by insurance physician	Clients
Ability to work according to insurance physician and own ideas about ability to work	Clients
Advice on RTW by insurance physicians and healthcare providers	Clients
Experience with contacting healthcare providers	Insurance physicians
Effects of contacting healthcare providers	Insurance physicians
Participatory approach	
Development of RTW action plan	Clients, labor experts, RTW coordinators
Identification of obstacles for RTW	Clients, labor experts, RTW coordinators
Thinking about solutions to overcome RTW obstacles	Clients, labor experts, RTW coordinators
Thinking about suitable work	Clients, labor experts, RTW coordinators
Relationship between health complaints and thinking about obstacles for RTW, solutions to overcome obstacles, and suitable work	Clients, labor experts, RTW coordinators
Own role in development RTW action plan	Clients, labor experts, RTW coordinators
Implementation of RTW action plan	Clients, labor experts, RTW coordinators
Looking for a job, based on RTW action plan	Clients
Experience with guidance by RTW coordinator	Clients
Experience with guidance by labor expert	Clients
Participation of client in developing RTW action plan	Labor experts, RTW coordinators
Collaboration between stakeholders in developing RTW action plan	Labor experts, RTW coordinators
Direct placement in a competitive job	
Support by vocational rehabilitation agency in job search	Clients
Effectiveness of job search by vocational rehabilitation agency	Clients, case managers
Effectiveness of own job search	Clients
Collaboration between professionals of SSA and of vocational rehabilitation agencies	Clients, RTW coordinators, case managers
Ways in which was searched for a suitable job	Clients, case managers
Ways in which a suitable job was offered to client	Clients, case managers
Collaboration with client in job search	Case managers
Other	
Contra-indications for participation in intervention	Insurance physicians
Delay in execution of intervention	Labor experts, RTW coordinators

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Effectiveness of a return to work program for workers without an employment contract, sick-listed due to common mental disorders: A randomized controlled trial

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Abstract

Objectives Both the presence of mental health problems and the absence of an employment contract have been related to long-term sickness absence and unemployment, indicating a need for return to work (RTW) interventions. Our aim was to study the effectiveness of a new participatory supportive RTW program for workers without an employment contract, sick-listed 2–14 weeks due to a common mental disorder, in comparison with usual care.
Methods A participatory approach, integrated care and direct placement in a competitive job were part of the new program. The primary outcome measure was duration until first sustainable RTW in competitive employment. Cox regression analysis was applied to study this outcome. Secondary outcome measures were average working hours, duration until any type of employment, sickness benefit duration, and perceived health and functioning.
Results In total, 186 participants were included in the study and randomly allocated to an intervention group (N=94) or control group (N=92). A hazard ratio of 1.15 (95% CI 0.61–2.16) for duration until first sustainable RTW indicated no significant effect of allocation to the new program, compared to usual care. Furthermore, no significant differences were found in favor of the intervention group on any secondary outcome.
Conclusions Compared to usual care, the new program did not result in a significant shorter duration until first sustainable RTW. However, due to low protocol adherence, it remains unclear what the results would have been if the program had been executed according to protocol.

Introduction

Mental health problems are prevalent in the working-age population of many developed countries [1]. Important consequences are high rates of sickness absence and unemployment, resulting in enormous societal costs [1] and individual suffering [2, 3]. Common mental health problems are mild-to-moderate depressive, anxiety, and stress-related complaints, which have also been described as common mental disorders (CMD) [1]. The large impact of CMD on society has led to a growing attention in recent literature for the development and evaluation of interventions that aim to promote return to work (RTW) of workers on sick leave due to a CMD [4–14]. Many of these studies focused on sick-listed employees, ie, workers with an employment contract.

Up to now, little attention has been paid to the development and evaluation of RTW interventions for sick-listed workers without an employment contract, such as temporary agency workers, those with an expired fixed-term contract, and unemployed workers [15]. This is an important concern as these workers seem to have a more vulnerable position in the labor market. Compared to sick-listed employees, they appear to be at risk of longer disability episodes [16, 17]. Moreover, in the last decennia, flexible forms of employment – such as temporary employment – have globally expanded [18, 19].

In the Netherlands, sick-listed workers without an employment contract are entitled to sickness benefit payment and occupational healthcare (OHC) by the Dutch Social Security Agency (SSA). Within this group, mental health problems are the most common reason for sick-listing [20, 21]. Often these workers experience several (psychosocial) RTW barriers and have a negative perception of their health condition [22]. In many cases, the absence of a workplace to return to is the main RTW obstacle [23].

A participatory supportive RTW program was developed to promote RTW of workers who filed a sickness benefit claim at the Dutch SSA due to a CMD. The program was based on an existing participatory approach, which had previously shown promising results among a similar group of workers sick-listed due to musculoskeletal disorders [24]. Direct placement in a competitive job by a vocational rehabilitation agency was added to the program to overcome the main RTW obstacle, ie, the absence of a workplace. Moreover, through application of an integrated care approach, collaboration between OHC

professionals of the Dutch SSA and (mental) healthcare providers was stimulated within this new program.

In this study, we present the effects of the participatory supportive RTW program. The main aim of this study was to evaluate the program's effectiveness in reducing the duration until first sustainable RTW in competitive employment, compared to usual OHC by the Dutch SSA. Secondary outcome measures were average working hours, duration until RTW in any type of employment, sickness benefit duration, and perceived physical and mental health and functioning.

Methods

Study design and setting

The study design consisted of a randomized controlled trial (RCT) with two arms – an intervention and control group – and a follow-up period of 12 months. Titled the "Co-WORK study", this trial was conducted in collaboration with seven offices of the Dutch SSA, located in three districts, and three vocational rehabilitation agencies. The Medical Ethics Committee of the VU University Medical Center approved the study design and all participants signed informed consent. The trial was registered at the Dutch Trial Register (Nederlands Trial Register) (NTR3563).

Study population and recruitment

Sick-listed workers (18–64 years), who applied for a sickness benefit at the Dutch SSA due to the (partial) absence of an employment contract and belonged to one of the participating SSA offices, received an invitational letter together with a short questionnaire 1–2 weeks after being sick-listed. Because during recruitment it was no longer possible to recruit on the basis of a registered mental health complaint, every newly sick-listed worker received an invitation and was asked to indicate whether he/she was sick-listed due to mental health problems. Furthermore, the short questionnaire consisted of a screener for distress [25], questions about the intention to return to work despite ongoing health complaints, and about the date of sick-listing. The RTW intention was measured on a 5-point Likert scale with responses: "certainly not", "probably not", "maybe", "probably", and "certainly". Sick-listed workers could only

participate if they experienced an elevated level of distress and were sick-listed for ≤14 weeks. Exclusion criteria included: 1. not being able to complete questionnaires written in the Dutch language; 2. having a conflict with the SSA regarding a sickness benefit claim or a long-term disability claim; 3. the presence of a legal conflict, eg, an ongoing injury compensation claim; 4. a sickness absence episode due to a CMD within one month before the current sickness benefit claim; 5. already having received usual OHC since the start of the current sickness absence period; 6. pregnancy, up until three months after delivery; 7. no signed informed consent form; and 8. probably/certainly not having the intention to return to work despite ongoing health complaints. This latter criterion was based on findings of two earlier studies [12, 24], which showed that sick-listed workers without this positive RTW intention require another type of intervention [12]. Sick-listed workers who were willing to participate and met the criteria for eligibility, were contacted by the researcher by telephone to screen for other in- and exclusion criteria.

After randomization, intervention group participants could still be excluded from participation in the RTW program in case their insurance physician assessed a (medical) contra-indication for participation. However, these individuals remained in the intervention group, based on the intention-to-treat principle.

Randomization and blinding

Randomization was performed at participant level. To ensure an equal distribution, pre-stratification was applied to different types of workers (before sick-listing) – ie, unemployed, temporary agency, and fixed-term contract worker – and the three participating SSA districts. A block randomization table with a fixed block size of four was generated for each stratum, based on schemes with random permuted numbers. Randomization was performed by a research assistant during an intake meeting with the participant.

Blinding participants and professionals for the randomization result was not possible due to the nature of the intervention. To minimize bias caused by self-report, we collected registered data from the SSA when possible. A research assistant entered all data into a database using a unique research number for each participant to guarantee blinded analyses by the researcher.

Interventions

Dutch Social Security Agency usual care

The Dutch SSA provides OHC in a team of professionals, consisting of a RTW coordinator, an insurance physician and a labor expert. The RTW coordinator investigates why the sick-listed worker thinks that he/she is unable to work. He/she monitors the full vocational rehabilitation process and refers the worker to the insurance physician or labor expert if necessary. The insurance physician is encouraged to follow the guidelines for OHC of the Dutch Society of Occupational Medicine. He/she advises the sick-listed worker about recovery and RTW based on a medical problem analysis. If necessary, he/she refers to further treatment options to prevent work disability. The labor expert provides vocational rehabilitation support and advises the sick-listed worker about RTW options, using his/her expertise of the labor market. He/she can decide to refer the sick-listed worker for additional support, such as assistance from a vocational rehabilitation agency.

The return to work program

Participants of both groups received usual OHC from the SSA. However, participants in the intervention group were referred to a more standardized form of OHC that started early after sick-listing, ie, the participatory supportive RTW program.

Within two weeks after allocation of the participant to the program, the RTW coordinator conducts a first analysis followed by a medical problem analysis by the insurance physician. Subsequently, the latter contacts the participant's healthcare provider(s) to agree on treatment and RTW. The RTW coordinator encourages the participant to play an active role in his/her own vocational rehabilitation process and to list all RTW obstacles. This list is then used as a starting point for a meeting between the worker and the labor expert, in which all obstacles are jointly prioritized. Also the RTW coordinator, with help from the labor expert, makes a list of RTW obstacles facing this particular worker. Subsequently, in the following two weeks, the participant has another meeting with both the RTW coordinator and the labor expert, during which they jointly search for solutions to overcome the prioritized obstacles and discuss suitable work. When consensus is reached, solutions and suggestions to find suitable work are summarized in a RTW action plan. During the making of this action plan, the participant's

responsibility in implementing the action plan is emphasized. To facilitate the job search, the participant is referred to a vocational rehabilitation agency. Within another four weeks, this agency offers the participant ≥2 competitive jobs with a minimum contract period of three months, matching with the RTW action plan. The RTW coordinator monitors the process and refers the participant to another vocational rehabilitation agency for additional support if necessary.

More information about the study design and setting, procedures used for recruitment, randomization and blinding, the sample size calculation, and the participatory supportive RTW program can be found in the study protocol [26].

Assessment of protocol adherence and contamination

We used findings of our previous process evaluation to assess the number of intervention group participants that participated in each step of the program. These findings have been described in more detail elsewhere [27]. For all participants, we assessed both registered information about consultations with SSA professionals and self-reported information about additional vocational rehabilitation support or medical co-interventions.

Outcome measures and data collection

Data regarding paid employment, sickness absence, and type of worker were collected from the SSA database. Additional data on RTW and sickness absence were assessed every three months using questionnaires. Other outcomes were measured every six months. Possible confounders were measured at baseline, after informed consent was signed and prior to randomization.

Primary outcome measure

The primary outcome was the duration in calendar days from the day of enrollment in the study until first paid employment in a regular work-setting for ≥28 consecutive calendar days. It was possible that the participant was still partially at work at the time of enrollment in the study. In that case, the participant was considered to have reached the outcome if he/she had returned to work for the hours for which he/she had been sick-listed. Our RTW assessment was not restricted to full work resumption. The first and third authors assessed

this outcome while the second author checked this interpretation on inconsistencies in ten random cases.

Secondary outcome measures

To assess the average working hours per week, we divided the total working hours by the total number of weeks in competitive employment during follow-up.

To measure the duration until first employment in any type of work, both RTW in paid and unpaid labor were included, regardless of the duration of the work resumption.

In line with Vermeulen et al [24], the sickness benefit period was defined as the duration between the day of enrollment in the study until ending of this benefit for ≥28 days.

The 4-Dimensional Symptom Questionnaire (4DSQ) [28] and the Dutch translation of the 36-item Short Form Health Survey (SF-36) [29] were used to assess perceived mental and physical health and functioning. The 4DSQ consists of four scales measuring perceived symptoms of distress, anxiety, depression and somatization [28]. The SF-36 consists of eight scales: physical functioning, role limitations due to physical health, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health. These scales were used to construct two summary component scores (physical and mental) for our population relative to standard scores, with a standard mean of 50 [29, 30].

Possible confounders

Earlier studies found associations between RTW or sickness absence duration of sick-listed workers with mental health problems and their age [16, 31, 32], type of worker [16, 32], RTW expectations [31], and RTW intention [12, 24]. Therefore, information was gathered about these possible confounders. We also assessed other demographic characteristics, ie, gender and education. To assess type of worker we assessed type of worker before sick-listing, the presence of an employment contract at baseline, the work schedule in the participant's last job, the average number of working hours a week and the years worked in this kind of employment.

The participant's expectations of being able to fully return to work in the next six months were assessed on a 5-point Likert response scale and dichotomized into being "very sure/sure" or "not sure nor unsure/unsure/very unsure".

RTW intention and underlying behavioral determinants, ie, Attitude, experienced Social influence and self-Efficacy regarding RTW (ASE), were assessed with a questionnaire developed earlier by Van Oostrom et al [12, 33]. The same item used earlier in the screening questionnaire was used again to assess the RTW intention despite ongoing health complaints.

In addition, the relation between health complaints and work resumption was assessed with the fear avoidance beliefs subscale of the Dutch Work Reintegration Questionnaire [34, 35].

Statistical analyses

When multiple-scale questionnaires were used, first sum scores were computed for each scale. In case of missing items, the average score of the items in the same scale were imputed for the missing items, but only in cases where at least half of the items in this scale were valid.

Descriptive statistics were used to compare baseline characteristics of the intervention and control groups. T-tests for continues variables and Pearson Chi-Square tests for categorical variables were performed to assess the statistical significance of possible differences between groups.

Techniques originating from survival analysis were used to analyze the effects of allocation to the intervention or control group on duration until first sustainable RTW in a competitive job, duration until RTW in any type of work, and the sickness benefit duration. Kaplan Meier curves were plotted to describe the duration until these outcomes in both groups. When no median duration could be assessed because <50% of the participants eventually reached the outcome, we instead assessed the duration until the outcome was reached by ≥25% of the participants. Subsequently, Cox regression analysis was used to estimate the hazard ratio's (HR) for these outcomes and corresponding 95% confidence intervals (CI). In case the proportion between the Kaplan Meier curves seemed to change over time, we investigated whether the HR were significantly different for different time periods by adding an interaction term between group and a time dependent covariate to the model.

Linear regression analyses were applied to investigate differences between the two groups in the average working hours per week.

Linear mixed models were used to investigate the longitudinal effect on perceived mental and physical health and functioning. The models were adjusted for differences in outcomes at baseline. To adjust for the dependency of multiple measurements in time within the same participant, a random intercept was included. We also accounted for possible clustering at the level of participating SSA offices. Random coefficients were added to the model at this level in case the difference between the results of the -2 log (restricted) likelihood tests of the new and previous model differed ≥3.84 points, after adding a random intercept, and ≥5.99 points, after adding a random slope.

All analyses were adjusted block-wise for possible confounding factors. The analyses were applied according to the intention-to-treat principle. In addition, per-protocol analyses were performed. For all analyses a P-value of <0.05 (2–tailed) was considered statistically significant. The analyses were performed in SPSS 22 (IBM, Armonk, NY, USA).

Results

Participant flow

The flow of sick-listed workers in the Co-WORK study is illustrated in Figure 1. Between March 2013 and September 2014, 9822 sick-listed workers were approached for participation in the study. In total, 186 participants were included in the study and randomly allocated to an intervention (N=94) or control (N=92) group.

Loss to follow-up

Data about paid employment, sickness absence, type of worker, and SSA consultations could be collected from the SSA database for all participants (100%). Availability of self-reported data within each group is illustrated in Figure 1.

Baseline characteristics

Table 1 presents the baseline characteristics of participants in both groups. There were mainly small, non-significant differences between the groups, except for the expectation regarding RTW within six months (P<0.01).

Occupational healthcare

Figure 1 illustrates the OHC during follow-up in both groups. Only 36 intervention group participants (38%) continued with the program after the medical problem analysis. These participants are referred to as the "per-protocol group". In case of a medical contraindication (N=26), the participant continued in usual OHC instead. Participants whose sickness benefit had already ended or was likely to end early after randomization because recovery of workability was established (N=20), were by law (soon) no longer entitled to OHC by the SSA, and as such could no longer participate in the program.

Figure 1 shows how many of the per-protocol participants (N=36) participated in each step of the program. The figure also shows the number of participants in the intervention and control groups that had ≥1 consultations with an SSA professional as well as information about referral to a vocational rehabilitation agency and medical co-interventions.

Primary outcome measure

In the intervention and control groups, 25 (27%) and 24 (26%) participants, respectively, returned to work sustainably during follow-up. After 327 days in the intervention group and 302 days in the control group, ≥25% of the participants had returned to work sustainably. The range between the minimum and maximum duration until this outcome in the intervention and control group was respectively 23–336 days and 8–321 days. Figure 2 illustrates the unadjusted Kaplan Meier curves for time until first sustainable RTW in the two groups. Table 2 presents the crude and adjusted HR. In none of the models a significant effect of allocation to the intervention compared to the control group was found. Also the per-protocol analysis showed no significant effect.

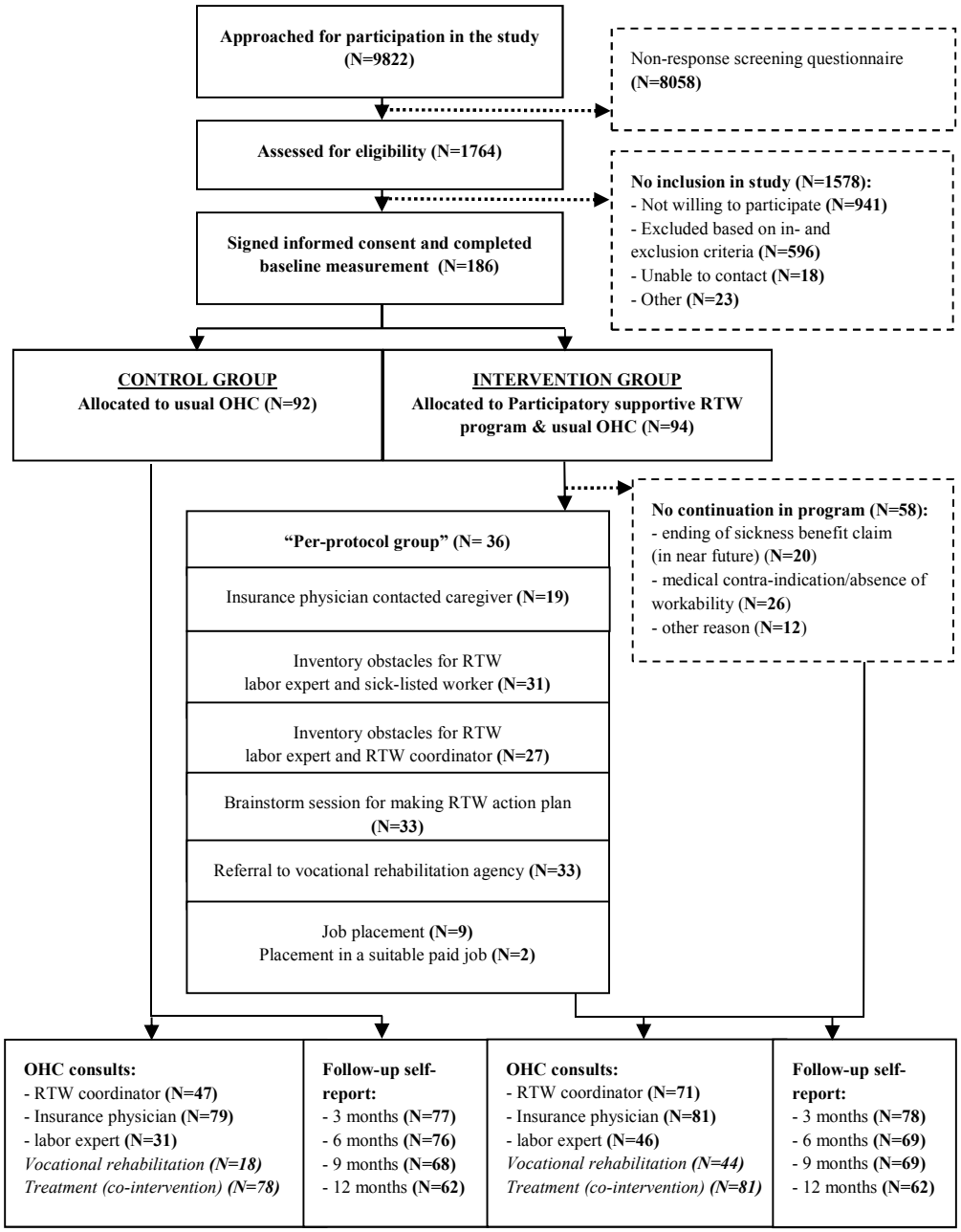

Figure 1 Flow diagram of participants in the Co-WORK study

Table 1 Baseline characteristics

Variable	Intervention group (N=94)				Control group (N=92)			
	N	%	Mean	SD	N	%	Mean	SD
Demographic characteristics								
Gender, Female	45	48			47	51		
Age in years			45.7	10.6			46.3	10.0
Education, Low [a]	26	28			23	25		
Type of worker								
Type of worker before reporting sick								
Unemployed worker	88	94			85	92		
Temporary agency worker	4	4			2	2		
Fixed-term contract worker	2	2			5	5		
Employment contract at baseline, Yes	11	12			14	15		
Work schedule in last job, day work	72	77			75	82		
Working hours per week in last job [b]			32.6	11.6			31.4	10.8
Years worked in last job [c]			10.0	10.0			8.7	9.6
Expectation regarding ability for full RTW in 6 months, (very) certain	4	4			16	17		
ASE [d]								
Intention to RTW, Yes	78	83			81	88		
Attitude (6–30 score)			15.7	5.2			14.9	4.2
Normative beliefs (4–20 score)			12.0	3.1			12.6	2.6
Social modelling (2–10 score)			4.8	1.9			4.8	1.5
Self-efficacy (2–10 score)			6.3	1.8			6.2	1.6
Fear avoidance beliefs (4–40 score) [e]			29.0	6.9			28.5	7.0
4DSQ [f]								
Distress (0–32 score)			25.8	5.1			26.3	5.4
Depression (0–12 score)			6.7	3.7			6.8	3.9
Anxiety (0–24 score)			10.7	6.1			9.8	6.7
Somatization (0–32 score)			14.9	5.9			15.5	7.2
SF-36 [g]								
Physical component summary score			46.4	9.5			47.7	9.3
Mental component summary score			21.0	8.5			22.1	9.1

ASE=Attitude, Social influence and self-Efficacy; 4SDQ=4-Dimensional Symptom Questionnaire; SF-36=36-item Short Form Health Survey; SD= Standard deviation; N=Number,

[a] Low educational level included no education, primary school or lower vocational education

[b] N (total) is 183 due to missing cases

[c] N (total) is 185 due to one missing case

[d] A lower score on these scales corresponds with a more positive attitude regarding RTW (attitude), the belief that other people think work resumption is important (normative beliefs), finding it more important what other people think (social modelling) and a stronger feeling of self-efficacy regarding RTW (self-efficacy)

[e] A higher score on this scale indicates a stronger belief that health complaints could interfere with RTW

[f] A lower score on these scales corresponds to fewer complaints

[g] A higher score on these scales than standard mean of 50 corresponds to better perceived health or functioning

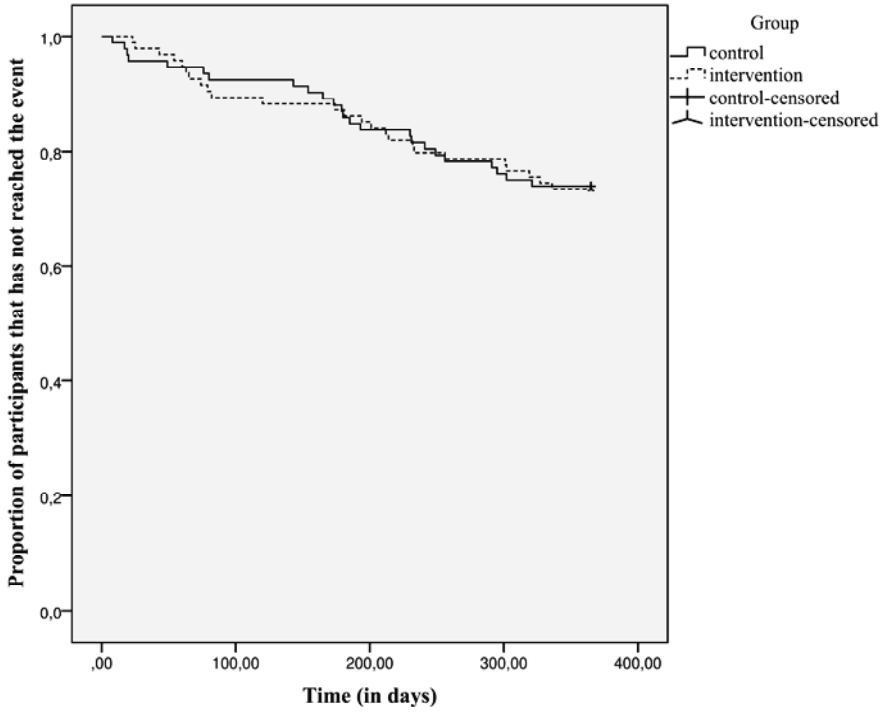

Figure 2 Kaplan Meier curves for duration until first sustainable RTW

Table 2 Results of the Cox Regression analyses

	HR [a]	95% CI	P	HR [b]	95% CI	P	HR [c]	95% CI	P	HR [d]	95% CI	P
Time to first sustainable RTW in competitive employment	1.02	0.58-1.78	0.95	1.00	0.57-1.75	0.99	0.98	0.55-1.77	0.96	1.15	0.61-2.16	0.67
Time to first RTW in any type of employment	0.88	0.56-1.37	0.56	0.87	0.56-1.36	0.54	0.92	0.57-1.47	0.72	0.99	0.58-1.67	0.96
Sickness benefit duration (days)												
≤240	0.75	0.47-1.19	0.22	0.76	0.47-1.21	0.24	0.75	0.46-1.22	0.25	0.74	0.45-1.23	0.24
>240	2.19	0.84-5.70	0.11	2.11	0.81-5.51	0.13	2.16	0.82-5.70	0.12	2.27	0.85-6.07	0.10

N=Number; HR=hazard ratio; 95% CI= 95% confidence interval; P= P-value
Reference group is the control group in all models
[a] Crude HR
[b] Adjusted for baseline differences in demographic characteristics
[c] Adjusted for baseline differences in demographic characteristics + type of worker
[d] Adjusted for baseline differences in demographic characteristics + type of worker + RTW expectation + ASE + intention to RTW + fear avoidance beliefs

Secondary outcome measures

Working hours per week

Participants in the intervention and control groups who were employed during follow-up worked on average respectively 26.3 (standard deviation (SD) 12.6) and 25.6 (SD 14.1) hours per week, which did not differ significantly (adjusted B -0.62, 95% CI -10.83–9.59, P=0.90). Also the per-protocol analysis revealed no significant differences between groups.

Return to work in any type of employment

In total, 37 intervention group participants (39%) and 40 control group participants (43%) returned to work in paid or unpaid labor. After 181 and 167 days, ≥25% of the participants in the intervention and control groups, respectively, had reached this outcome. The range in duration until this outcome was 14–342 days in the intervention group and 8–348 days in the control group. Both the crude and adjusted HR are presented in Table 2. A significant effect of allocation to the intervention compared to the control group was found neither in these models nor the per-protocol analysis.

Sickness benefit period

The sickness benefit ended for 45 (48%) and 47 (51%) participants in the intervention and control groups, respectively. After 89 days, the sickness benefit had ended for ≥25% of the participants in both groups, with a range of 8–336 days in the intervention group and 14–329 days in the control group. The HR's for the intervention compared to the control group were found to differ significantly (P<0.05) before and after 240 days. Table 2 presents the crude and adjusted HR for both periods and shows no significant differences between groups. Results of the per-protocol analysis differed slightly.

This analysis revealed a significant delayed ending of the sickness benefit in the first 240 days for the per-protocol group in comparison with the control group (adjusted HR 0.30, 95% CI 0.12–0.75, P=0.01), followed by a non-significant trend towards an earlier ending of the sickness benefit in this first group after 240 days (adjusted HR 2.79, 95% CI 0.95–8.15, P=0.06).

Health related outcomes

Table 3 summarizes the results of the (adjusted) mixed-model analyses. We found no significant differences in health outcomes between the two groups. The per-protocol analyses also revealed no significant differences between the per-protocol and control groups.

Table 3 Results of the mixed model analyses

		Outcomes				Average intervention effect during follow-up											
		6 months		12 months													
		Mean	SD	Mean	SD	β [a]	95% CI	P	β [b]	95% CI	P	β [c]	95% CI	P	β [d]	95% CI	P
4DSQ [e]																	
Distress	I	19.1	8.4	17.5	10.1	-0.27	-2.54-2.01	0.82	-0.13	-2.37-2.10	0.91	0.20	-2.11-2.50	0.87	-0.10	-2.52-2.32	0.94
	C	20.1	8.7	17.9	10.0												
Depression	I	4.5	4.1	3.7	4.3	-0.10	-1.02-0.82	0.84	0.04	-0.95-0.86	0.92	-0.01	-0.94-0.92	0.98	0.0	-0.98-0.98	1.0
	C	4.5	4.0	4.6	4.2												
Anxiety	I	6.7	5.8	6.1	6.3	-0.88	-2.27-0.51	0.21	-0.83	-2.23-0.57	0.24	-0.92	-2.36-0.53	0.21	-1.05	-2.58-0.49	0.18
	C	7.8	6.8	6.9	7.4												
Somatization	I	12.5	7.2	12.1	7.6	0.28	-1.37-1.93	0.74	0.35	-1.30-2.0	0.68	0.59	-1.11-2.29	0.49	-0.09	-1.86-1.69	0.92
	C	12.8	7.2	11.4	8.0												
SF-36 [f]																	
Physcial	I	47.8	10.1	46.1	10.4	-0.19	-2.39-2.01	0.87	-0.45	-2.55-1.65	0.67	-0.47	-2.61-1.68	0.67	-0.69	-2.96-1.58	0.55
	C	47.7	9.0	48.3	10.6												
Mental	I	31.5	11.6	35.5	12.8	1.31	-1.93-4.54	0.43	1.12	-2.08-4.32	0.49	0.89	-2.35-4.13	0.59	1.59	-1.83-5.01	0.36
	C	31.5	12.3	32.8	13.6												

I=intervention group; C=control group N=Number; 4SDQ=4-Dimensional Symptom Questionnaire; SF-36=36-item Short Form Health Survey; SD= Standard deviation; 95% CI= 95% confidence interval; P= P-value

Reference group is the control group in all models

[a] Regression coefficient adjusted for baseline differences in outcome

[b] Regression coefficient adjusted for baseline differences in outcome + demographic characteristic

[c] Regression coefficient adjusted for baseline differences in outcome + demographic characteristics + type of worker

[d] Regression coefficient adjusted for baseline differences in outcome + demographic characteristics + type of worker + RTW expectation + ASE + intention to RTW + fear avoidance beliefs

[e] Improvement in mental disorder symptoms corresponds to a lower score

[f] Improvement in functioning or health status corresponds to a higher score

Discussion

Main findings

The present study showed no significant superior or adverse effect of allocation to the participatory supportive RTW program on the duration until first sustainable RTW in comparison with usual OHC by the Dutch SSA. Furthermore, no significant differences were found in favor of the intervention group on any secondary outcome.

Interpretation of findings

The absence of an intervention effect on the duration until sustainable RTW could be explained by implementation failure. A very low number of intervention group participants actually participated in the RTW program (N=36), and even in this per-protocol group, protocol adherence was only low to moderate [27]. We tried to enhance protocol adherence by a detailed protocol description and organizing follow-up training sessions for participating professionals. Still, the main stakeholders in our study experienced several barriers to the program's successful execution [36].

Some aspects of this implementation failure also played a role in the evaluation of other RTW programs, which reveals that improving OHC in daily practice is difficult. For example, a recent Dutch study by Audhoe et al [37] evaluating a new RTW program aimed at a comparable population, ie, non-permanent workers with psychological problems, also revealed low protocol adherence by Dutch SSA professionals and unsuccessful counseling by contracted vocational rehabilitation agencies. Their explanations for this low protocol adherence were similar to the barriers mentioned by the stakeholders in our study, namely, organizational constraints and limited availability of suitable workplaces [36, 37]. Furthermore, in a recent study on an integrated workplace intervention for Dutch workers with rheumatoid arthritis, Van Vilsteren et al [38] found that it was difficult to implement an integrated care approach. This is in line with an earlier Dutch study by Anema et al [39] that revealed limited collaboration between OHC professionals and other healthcare providers in the Netherlands.

An important consequence of the implementation failure in our study was less continuity in OHC than was prescribed in the protocol. Because continuity in OHC is considered important in enhancing RTW [40, 41], this may have influenced the effectiveness of the

new program. This means that it remains unclear what the results would have been if the program had been executed according to protocol.

Nevertheless, comparing the effectiveness of a participatory RTW program across studies reveals more promising results for sick-listed workers with physical complaints compared to those with mental health problems. To illustrate, in Canada and the Netherlands, beneficial effects of a participatory RTW program on work-related outcomes were found for sick-listed employees with low back pain [42–44] and on the duration until sustainable RTW of workers without an employment contract and sick-listed due to musculoskeletal disorders [24]. Whereas, in line with our findings, no superior (overall) intervention effect on the duration until sustainable RTW was found for Dutch sick-listed employees with a CMD [12], and an adverse effect of a very similar program was found for Danish sickness absence beneficiaries with mental health problems [7]. Furthermore, although we selected participants with positive RTW intentions and our analyses were adjusted for possible changes in this intention, findings were inconsistent with the beneficial intervention effect found for a similar subgroup of employees sick-listed due to a CMD with such positive intention at baseline [12]. This suggests a discrepancy in findings for sick-listed workers with a CMD who still have an employment contract and those who no longer have an employment contract.

Although implementation failure will have played a role in the discrepancy in findings between our and the aforementioned studies, this discrepancy may also suggest that our RTW program has not properly addressed specific challenges in improving RTW of workers without an employment contract, sick-listed due to a CMD. One important challenge may be doubts about the sick-listed worker's readiness to return to work. Our evaluation of the program's execution in practice revealed not only that the participating professionals questioned the sick-listed workers' RTW readiness, but also the sick-listed workers themselves were sometimes insecure about their capabilities [36]. This feeling of insecurity may reflect an anticipated stigma or fear-avoidance beliefs, both of which have been considered important risk factors for not returning to work [45, 46]. Another challenge was the absence of a workplace to return to. The lack of a clear RTW perspective complicated translating experienced mental health problems into concrete obstacles for RTW and finding practical solutions to overcome these obstacles [36]. Furthermore, many

of the participants in our study were already unemployed before reporting sick, which may have increased their distance from the labor market.

The presence of an adverse intervention effect on the sickness benefit duration, found in the per-protocol group of our present study, was also visible in Vermeulen et al's study [24], albeit not significant. In two ways, this finding can be related to SSA termination of OHC, once the sickness benefit ends. Firstly, intervention group participants, whose sickness benefit was likely to end soon after randomization according to the insurance physician, were excluded from participation in the new program as they were soon no longer entitled to OHC. As a consequence, the per-protocol group mainly consisted of participants whose sickness benefit was unlikely to end soon. Secondly, once participation in the program had started, the insurance physicians possibly first wanted to await the effectiveness of the new program before they terminated the sickness benefit.

Strengths and limitations of this study

A strength of this study is the assessment of both first sustainable RTW in paid employment and first RTW in any type of employment, which makes it possible to compare our results with results of multiple studies on RTW interventions. Moreover, our primary outcome may be considered robust because it only includes sustainable RTW [12, 24]. Finally, the assessment of these outcomes with the use of both registered SSA and self-reported data, minimizes possible bias caused by self-report.

A first limitation of this study is that, because of its pragmatic design, generalizing our results to other settings could be difficult. A second limitation is that we may have insufficiently addressed barriers for a successful execution of the participatory supportive RTW program before the trial began. More comprehensive intervention mapping or a pilot study prior to the trial could possibly have helped to overcome some of these barriers. A third limitation of this study is the absence of blinding of both participants and professionals for the randomization result. A last limitation is that invitations for participation in the study were sent to a very large number of sick-listed workers (N=9822) to be able to include the necessary number of participants in this study, as it was not possible to recruit participants solely based on a registered mental health problem [27].

Implications for practice and research

Based on the results of this study, we cannot recommend to implement the RTW program in the Dutch social security sector in its current form. Firstly, it will be necessary to overcome several barriers for a successful implementation. Secondly, it may be necessary to tailor the program to the specific needs and context of workers without an employment contract and sick-listed due to a CMD. Lessons may be learned from successful RTW interventions aimed at people with more severe mental illness, such as supported employment. Part of this approach are regular meetings between all stakeholders, including employment specialists and healthcare providers [1]. This approach is a good example of how to apply an integrated care approach so that treatment and vocational needs can be addressed simultaneously. Another characteristic of supported employment is ongoing support for both the worker and his/her employer during placement in work [1]. Similar support may also stimulate early and sustainable RTW of sick-listed workers with a CMD and may be an incentive for employers to hire these workers. This may help to overcome barriers resulting from a limited availability of suitable jobs. Placement in a suitable job could further be stimulated by offering subsidized workplaces, as Vermeulen et al [24] suggested earlier. Future research is needed to carefully consider these suggestions for developing a more suitable RTW intervention.

Concluding remarks

Compared to usual OHC, a participatory supportive RTW program did not result in a significant shorter duration until sustainable RTW of workers without an employment contract and sick-listed due to a CMD. Nevertheless, due to implementation failure, it remains unclear what the results would have been if the program had been executed according to protocol. For future evaluation of a RTW program for this type of worker, it will be important to identify and overcome barriers for a successful implementation in an early phase. Further research may also be needed to consider how the vocational needs of these vulnerable workers could be better addressed.

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A participatory supportive return to work program for workers without an employment contract, sick-listed due to a common mental disorder: an economic evaluation alongside a randomized controlled trial

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Abstract

Background Mental disorders are associated with high costs for productivity loss, sickness absence and unemployment. A participatory supportive return to work (RTW) program was developed in order to improve RTW among workers without an employment contract, sick-listed due to a common mental disorder. The program contained a participatory approach, integrated care and direct placement in a competitive job. The aim of this study was to evaluate the cost-effectiveness and cost-utility of this new program, compared to usual care. In addition, its return on investment was evaluated.

Methods An economic evaluation was conducted alongside a 12-month randomized controlled trial. A total of 186 participants was randomly allocated to the new program (N=94) or to usual care (N=92). Effect measures were the duration until sustainable RTW in competitive employment and quality-adjusted life years (QALYs) gained. Costs included intervention costs, medical costs and absenteeism costs. Registered data of the Dutch Social Security Agency were used to assess the duration until sustainable RTW, intervention costs and absenteeism costs. QALYs and medical costs were assessed using three- or six-monthly questionnaires. Missing data were imputed using multiple imputations. Cost-effectiveness analysis and cost-utility analysis were conducted from the societal perspective. A return on investment analysis was conducted from the social insurer's perspective. Various sensitivity analyses were performed to assess the robustness of the results.

Results The new program had no significant effect on the duration until sustainable RTW and QALYs gained. Intervention costs and medical costs were significantly higher in the intervention group. From the societal perspective, the maximum probability of cost-effectiveness for duration until sustainable RTW was 0.64 at a willingness to pay of about €10 000/day, and 0.27 for QALYs gained, regardless of the willingness to pay. From the social insurer's perspective, the probability of financial return was 0.18.

Conclusions From the societal perspective, the new program was neither cost-effective in improving sustainable RTW nor in gaining QALYs. From the social insurer's perspective, the program did not result in a positive financial return. Therefore, the present study provided no evidence to support its implementation.

Trial registration The trial was listed at the Dutch Trial Register (NTR) under NTR3563 on August 7, 2012.

Background

Mental disorders are associated with high costs for the individuals concerned, employers, the social security system and society as a whole. In Europe, the overall cost of mental disorders is estimated at 3-4% of the gross domestic product [1]. The majority of these costs is made outside the healthcare sector and is related to loss of potential labor supply, sickness absence, reduced productivity at work, and unemployment [1,2]. To illustrate, individuals with a severe mental disorder are 6 to 7 times less likely to be employed than individuals without such a disorder. The risk of unemployment is smaller when disorders are milder. Nevertheless, individuals with mild to moderate mental disorders, also known as common mental disorders (CMDs), are still 2 to 3 times less likely to be employed [1]. This is an important concern, as mental disorders are highly prevalent in the working-age population and around three-quarters of those affected by a mental disorder have a CMD [1]. Moreover, several Dutch studies comparing sick-listed workers without an employment contract with sick-listed employees revealed that the former often experience a worse health status and face more obstacles for return to work (RTW) [3]. As a result, these workers have an increased risk for long-term disability [4].

Despite the aforementioned association between mental ill health and unemployment, until now most intervention research aiming to improve work participation of workers sick-listed due to a CMD have assumed the presence of a workplace [5]. For this reason, the participatory supportive RTW program was developed. The aim of this program was to shorten the duration until RTW of workers without an employment contract who are sick-listed due to a CMD. This program was based on three best practices in occupational healthcare (OHC): a participatory approach, integrated care, and direct placement in a competitive job [6].

We evaluated the effectiveness of this new participatory supportive RTW program on the duration until sustainable RTW, in comparison with usual OHC in the Netherlands for sick-listed workers without an employment contract [7]. However, to make a business case for or against the intervention it is also important to evaluate the (additional) societal cost per unit of effect gained [8]. As decision-makers are often confronted with limited resources, they need to decide on the optimal allocation of resources to maximize a certain desired outcome or benefit [9]. Therefore, the aim of the present study was to conduct a cost-

effectiveness analysis (CEA) and a cost-utility analysis (CUA) to assess the (additional) societal costs per one day earlier sustainable RTW and per quality-adjusted life year (QALY) gained. In addition, we evaluated the financial return on investment (ROI) from the social insurer's perspective. In the Netherlands, the Dutch Social Security Agency (SSA) is responsible for sickness benefit payment and OHC for sick-listed workers without an employment contract. Because of this, the SSA is interested in the financial return of the new program. Our main research question was: what was the cost-effectiveness and cost-utility of the new participatory supportive RTW program from the societal perspective, in comparison with usual OHC? A second research question was: what was the ROI of the new program, compared to usual OHC, from the social insurer's perspective?

Methods

Study population and design

An economic evaluation was conducted alongside a 12-month randomized controlled trial (RCT), titled "The Co-WORK study", which took place between 2013 and 2015. The trial was carried out in collaboration with seven offices of the Dutch SSA, located in three districts, and with three vocational rehabilitation agencies. Participants were recruited via an invitational letter from the medical advisor of the Dutch SSA. This invitational letter was sent one to two weeks after sick-listing, so that an early intervention could take place. This has been considered important in the prevention of long-term sickness absence [10]. Because it was not possible to recruit on the basis of a registered mental health complaint, every newly sick-listed worker received an invitation. Sick-listed workers were asked to only respond to this invitation when they experienced mental health problems. Eligible for participation were workers 2–14 weeks sick-listed, who had applied for a sickness benefit at the Dutch SSA due to the (partial) absence of an employment contract, with mental health problems as the main reason for their claim. Other inclusion criteria were: an elevated level of distress, based on a distress screener [11], and the intention to return to work despite ongoing health complaints, as workers without this intention less likely seem to benefit from a participatory approach [12,13].

Participants were randomly allocated to an intervention or control group, after they had completed the baseline questionnaire. Before randomization, pre-stratification took place

based on type of worker before sick-listing (ie, unemployed worker, temporary agency worker, and fixed-term contract worker) and the three participating SSA districts. Schemes with random permuted numbers were used to create a block randomization table for each stratum, with fixed block sizes of four. A research assistant performed the randomization during an intake meeting with the participant. Due to the nature of the intervention, blinding participants and professionals for the randomization result was not possible.
More information about the study design and setting, in- and exclusion criteria for participation, recruitment procedures, randomization and blinding, and the sample size calculation can be found in the study protocol [6].

Interventions

Usual occupational healthcare

Usually, OHC is provided by a team of professionals from the SSA consisting of an insurance physician, a labor expert and a RTW coordinator. The OHC starts with an examination of the sickness benefit claim by the RTW coordinator. Subsequently, the RTW coordinator, the insurance physician and the labor expert together decide whether it is necessary for the sick-listed worker to visit the insurance physician and/or the labor expert for (medical) examination and/or advice on recovery and RTW. If necessary, the sick-listed worker can be referred to work disability oriented treatment or additional vocational rehabilitation support. The OHC that is actually delivered to the sick-listed worker is dependent on the sick-listed worker's progress in vocational rehabilitation.

The participatory supportive RTW program

All participants were entitled to usual OHC. In addition, participants in the intervention group were referred to a more protocolled form of OHC that started early after sick-listing and contained several best practices. Two of these practices, i.e. application of a participatory approach and integrated care, were new and one of these practices, i.e. placement in a competitive job by a vocational rehabilitation agency, is also possible in usual OHC, but has not been protocolled.
Table 1 briefly describes the content of this participatory supportive RTW program. A more detailed description is presented in the study protocol [6]. Participating professionals were

trained in the execution of this program during one session of approximately two and a half hours by the researchers, by means of a presentation and role plays. Training sessions were organized for each SSA office or district separately. In addition, follow-up sessions were planned at each SSA office, to evaluate the first cases and to discuss difficulties in applying the program in daily practice.

Table 1 The participatory supportive RTW program

Examination of sickness benefit claim and medical problem analysis *– within two weeks after allocation to the intervention team*
The RTW coordinator examines the sickness benefit claim, conform usual care
The insurance physician makes a medical problem analysis, conform usual care
Integrated care *– directly after the medical problem analysis*
The insurance physician contacts the healthcare provider(s) of the sick-listed worker by telephone to agree on treatment and RTW, and to stimulate cooperation during the vocational rehabilitation process
Participatory approach *– within two weeks after the medical problem analysis*
The labor expert supports the sick-listed worker and the RTW coordinator separately in identifying and prioritizing obstacles for RTW
The sick-listed worker and the RTW coordinator jointly search for solutions to overcome the main obstacles for RTW, and discuss suitable work
The labor expert tries to reach consensus between the sick-listed worker and the RTW coordinator, and summarizes the consensus-based solutions and suggestions for suitable work in a RTW action plan
The insurance physician makes adjustments to the RTW action plan, if necessary
The labor expert sends the final action plan to all stakeholders involved, and underlines the sick-listed worker's own responsibility to implement the action plan
Direct placement in a competitive job *– within four weeks after making a RTW action plan*
The RTW coordinator refers the sick-listed worker to a vocational rehabilitation agency to facilitate the job search
The vocational rehabilitation agency offers the sick-listed worker ≥2 suitable competitive workplaces with a minimum contract period of 3 months, matching the RTW action plan
The sick-listed worker is placed in a suitable competitive workplace
Evaluation *– within four weeks after making a RTW action plan*
The RTW coordinator contacts the sick-listed worker to evaluate the implementation of the RTW action plan
The RTW coordinator contacts the vocational rehabilitation agency to inquire if the sick-listed worker has been placed in a suitable workplace
The sick-listed worker is referred to two other vocational rehabilitation agencies for additional vocational support, if necessary

Effect measures

Duration until sustainable RTW

The primary effect measure was duration until sustainable RTW in a competitive job, defined as the duration in calendar days from the day of randomization until (partial) work resumption for at least 28 calendar days in a regular work setting for which payment is received at the market rate [6]. When the participant was only partially sick-listed, he/she was considered to have reached the outcome when he/she had (partially) returned to work for the hours he/she had been sick-listed for. For participants who had not reached the outcome, the total follow-up time of 365 days was taken into account.

Data about paid employment is registered continuously by the Dutch SSA, and was collected from this database after one year follow-up. Every three months, starting at baseline, questionnaires were used to collect additional data on work resumption, to facilitate interpretation of the registered data.

Quality-adjusted life years

At baseline, and after 6 and 12 months, the EuroQol-5D-3L [14] was used to assess quality of life. Scores on the five "health dimension" items (range 1–3) in this questionnaire were translated into a utility score (on a scale of 0–1, from equal to death to equal to full health) using the Dutch tariff [14]. QALYs were calculated by multiplying the obtained utility scores with the duration in this health state, using linear interpolation between measurement points.

Resource use and valuation

Intervention costs

Table 2 gives an overview of the applied cost categories and corresponding unit prices for determining intervention costs. Data on applied OHC during follow-up (ie, the number of consults with professionals from the Dutch SSA and referrals by the SSA for additional support) were obtained from the SSA database. Consults were valued using labor costs (including overhead) of the SSA professionals. Costs for additional support were valued using market prices, which were obtained from the SSA database as well.

Costs for the training in the participatory supportive RTW program were estimated using data on the number and duration of provided training sessions, as well as labor costs (including overhead) of SSA professionals attending the sessions, and the researchers providing the sessions.

Table 2 Assessment of intervention costs

Cost categories	Unit Prices
Applied OHC by the Dutch SSA – *Intervention and control group*	
Number of consults with OHC professionals from the Dutch SSA	
RTW coordinator	€58.50/hour
Insurance physician	€106.20/hour
Labor expert	€80.60/hour
Referrals by the SSA to work disability oriented treatment or additional vocational rehabilitation support	Market price
Training in the participatory supportive RTW program – *Intervention group*	
Number of hours attending the training	
RTW coordinator	€58.50/hour
Insurance physician	€106.20/hour
Labor expert	€80.60/hour
Number of hours providing the training	
Junior researcher	€33.30/hour
Senior researcher	€67.90/hour
Professor	€124.90/hour

Medical costs

Medical costs were assessed every three months using The Trimbos/iMTA questionnaire for costs associated with psychiatric illness (Tic-P) [15], measuring resource use with a 3-month recall period. The questionnaire included primary healthcare (ie, consults with a general practitioner, allied healthcare, and complementary medicine), secondary healthcare (ie, specialized healthcare, and hospitalization) and the use of medication. As for the use of medication, only the use of psychotropics, excluding antipsychotics, was included. Healthcare utilization was valued using Dutch Standard Costs [16] or, if not available, prices according to the professional organizations. Prices provided by the Dutch Society of Pharmacy [17] were used to value medication use.

Absenteeism costs

From the societal perspective, absenteeism costs were estimated by considering productivity loss. Because all participants were (partially) unemployed at the time of sick-listing, productivity loss could not be estimated based on sickness absence days from work.

Instead, our starting point was the maximum number of productive hours for a Dutch employee in full-time employment (36 hours/week), accounting for holidays and other days off, which was 1540 hours per year [16]. This number was regarded as the maximally possible productivity loss. The participants' level of productivity loss was estimated by subtracting the total number of hours in paid employment during follow-up, obtained from the SSA database, from the aforementioned maximum duration of productivity loss. We used the Human Capital Approach (HCA) to value productivity loss, by multiplying the loss of productivity in hours by the estimated price of productivity loss for a Dutch worker per hour, based on sex and age [16].
From the social insurer's perspective, absenteeism costs were calculated using the real costs for sickness benefit and employment benefit payment during follow-up, obtained from the SSA database.

All costs were converted to 2014 Euros using consumer price indices [18]. As the follow-up of the trial was one year, discounting of costs and effects was not necessary.

Statistical analyses
Analyses were performed according to the intention-to-treat principle. Statistical significance was set at $P<0.05$. Data were analyzed using Stata (V12, Stata Corp, College Station, TX). Descriptive statistics were used to compare baseline characteristics between the intervention and control group, as well as between participants with complete and incomplete data. Missing values for costs and effects were imputed separately for the intervention and control group using multiple imputations, through Predictive Mean matching. In total, five complete datasets were created (loss of efficiency≤5%) [19]. All of the imputed datasets were analyzed as specified below, after which pooled estimates were calculated using Rubin's rules [20].

Societal perspective: cost-effectiveness and cost-utility analyses
The CEA and CUA were conducted from the societal perspective, which means that all costs related to the intervention were taken into account irrespective of who pays or benefits. However, absenteeism costs were excluded from the CEA, as these costs could be considered as a proxy for the effect measure (ie, time to sustainable RTW). Effect

differences, in terms of duration until sustainable RTW and QALYs, and cost differences between the intervention and control group were analyzed simultaneously using seemingly unrelated regression (SUR). Hereby, cost and effect difference estimates could be adjusted for their possible correlation [21]. Furthermore, all estimates were corrected for possible prognostic factors for RTW as identified in the existing literature, ie, demographic characteristics, type of worker before sick-listing, RTW expectation, RTW intention, fear avoidance beliefs, and Attitude, Social influence and self-Efficacy (ASE) regarding RTW [12,13,22-24]. All these possible prognostic measures were assessed at baseline. Because of the skewness of the cost data, 95% confidence intervals (CIs) surrounding the cost-differences were estimated using bias-corrected and accelerated (BCA) bootstrap intervals with 5000 replications. Subsequently, incremental cost-effectiveness ratios (ICERs) were calculated by dividing the corrected mean cost differences by those in effects. By plotting bootstrapped incremental cost-effect pairs (CE-pairs) on cost-effectiveness planes (CE-planes), the uncertainty surrounding the ICERs was graphically illustrated [25]. Cost-effectiveness acceptability curves (CEACs) were plotted, presenting the intervention's probability of cost-effectiveness at different values of willingness to pay [26].

Social insurer's perspective: ROI analyses

ROI analyses were performed from the social insurer's perspective. Costs were defined as the mean difference in intervention costs (ie, differences in costs for applied OHC and costs for the training in the participatory supportive RTW program). Benefits were defined as the mean difference in absenteeism costs between the intervention and control group (ie, the mean difference in paid sickness benefits and unemployment benefits). Positive benefits indicated reduced spending. Costs and benefits were estimated using SUR analyses, and corrected for the same possible confounders as described above. The 95% CIs surrounding costs and benefits were estimated using bias-corrected and accelerated (BCA) bootstrap intervals with 5000 replications. Three ROI-metrics were calculated; 1. Net Benefits (NB); 2. Benefit Cost Ratio (BCR); and 3. Return on Investment (ROI).

NB = Benefits – Costs
BCR = Benefits / Costs
*ROI = ((Benefits – Costs) / Costs) * 100*

Financial returns are positive when NB>0, BCR>1, and ROI>0% [27-29]. To quantify the precision of these metrics, 95% bootstrapped CIs were estimated using 5000 replications. Subsequently, the probability of financial return was estimated based on the proportion of bootstrapped NBs, BCRs, and/or ROIs, indicating cost savings [30].

Sensitivity analyses

To assess the robustness of the results, five sensitivity analyses (SA) were performed. First, analyses were performed using the complete-cases only (SA1). Second, analyses were performed excluding healthcare outliers, ie, cases in which expenses for secondary care were above €10 000 (SA2). Third, per-protocol analyses were performed, comparing intervention group participants who had actually started with the participatory supportive RTW program after the medical assessment with control group participants (SA3). Finally, for the CEA and CUA only, two additional sensitivity analyses were performed in which the Friction Cost Approach (FCA) was used instead of the HCA to value productivity loss. According to this approach, organizations need a certain period to replace a sick-listed worker (ie, friction period). When a sick-listed worker is replaced, productivity loss stops. In the Netherlands, the estimated friction period was assumed to be 23 weeks [16]. More recently, however, a friction period of 12 weeks has been assumed [31]. We accounted for both friction periods, which means that when productivity loss exceeded the friction period of 23 or 12 weeks, costs were truncated at the costs of 23 or 12 weeks of productivity loss in SA4 and SA5, respectively.

Results

Participants

A total of 186 participants were randomly allocated to the intervention (N=94) or control group (N=92). Figure 1 illustrates the flow of participants in the Co-WORK study. Data on QALYs were complete for 58% of participants (N=107; 53 intervention group participants and 54 control group participants). Complete data on medical costs was obtained for 47% of participants (N=88; 43 intervention group participants and 45 control group participants). Data on the primary effect measure and all remaining cost categories were complete for all participants. Table *A1* (Appendix) presents the baseline characteristics for intervention and

control group participants with complete and incomplete baseline and follow-up data. A relevant difference was found between the RTW expectancy in the intervention and the control group, indicating a more certain expectancy to RTW in the control group. Relevant differences in age and the RTW intention were found between complete and incomplete cases in both groups. In the control group, more respondents with complete than incomplete data still had an employment contract at baseline.

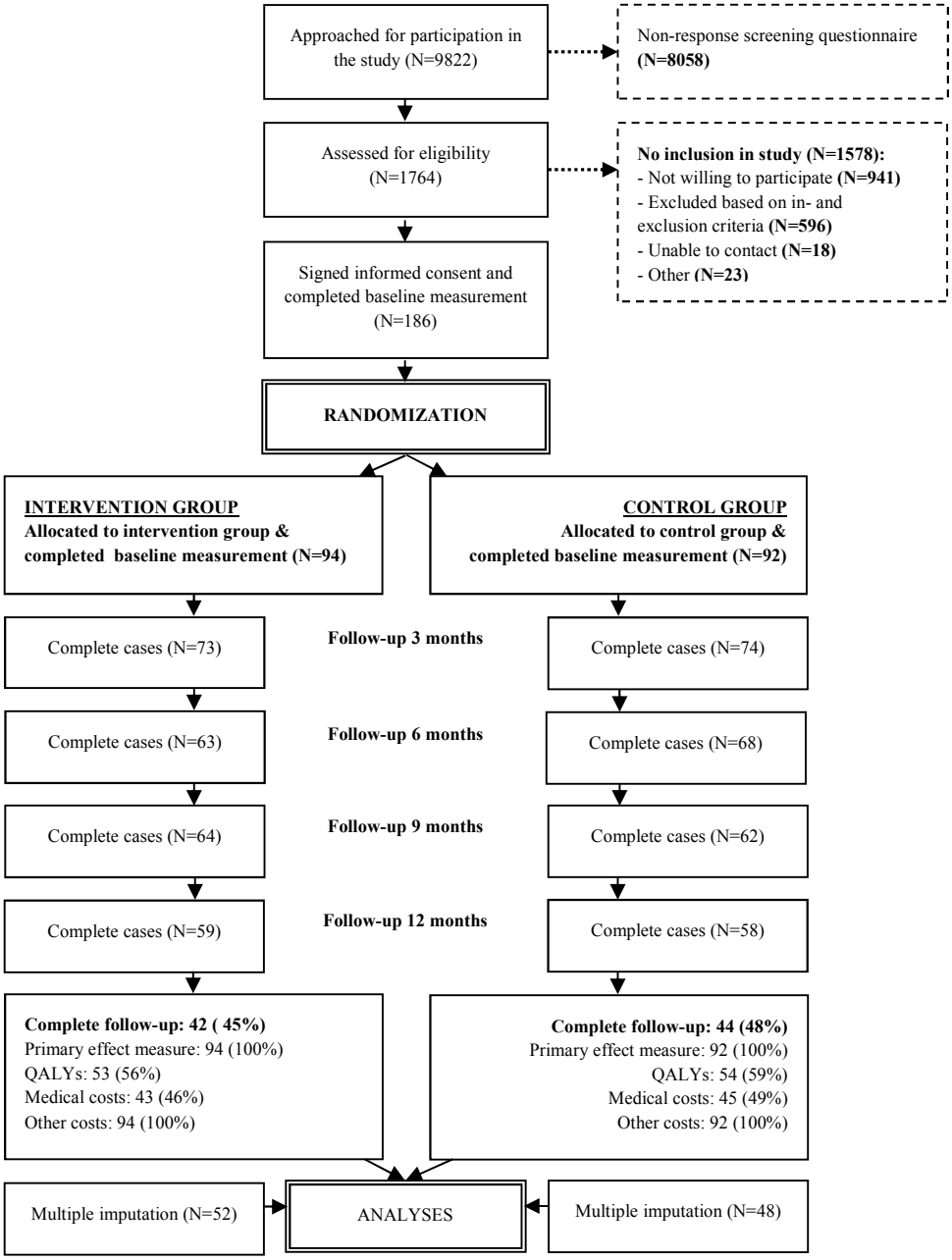

Figure 1 Flow of participants in the Co-WORK study

Effectiveness

Small and non-statistically significant differences in effects were found between the intervention and control group. In the intervention group, sustainable RTW was reached on average 6.6 days earlier (95% CI -37.8–24.6) compared with the control group, and the number of QALYs gained was on average 0.01 points lower (95% CI -0.08–0.06).

Costs

Additional file 2 (Table *A2*, Appendix) presents the cost differences between the intervention and control group from the societal perspective. In the corrected model, average costs for OHC consults, total intervention costs, secondary care costs, total medical costs, and total societal costs (excluding absenteeism costs) were significantly higher in the intervention group.

Societal perspective

Cost-effectiveness

Additional file 3 (Table *A3*, Appendix) presents the results of the cost-effectiveness and cost-utility analysis. For duration until sustainable RTW, an ICER of -€487 was found, indicating that a societal investment of €487 was needed per one day earlier sustainable RTW. The majority of incremental CE-pairs (67.3%) was located in the northeast quadrant of the CE-plane (Table *A3*, Figure 2), indicating that the intervention was on average more costly and more effective. The wide distribution of incremental CE-pairs in this plane illustrates a large level of uncertainty around the cost-effectiveness estimate. Figure 3 shows that when the willingness to pay for one day earlier RTW is €0, the probability that the participatory supportive RTW program can be considered cost-effective compared to usual OHC is about zero. This probability increases with an increasing willingness to pay, until it reaches a maximum probability of about 0.64 at a willingness to pay of about €10 000.

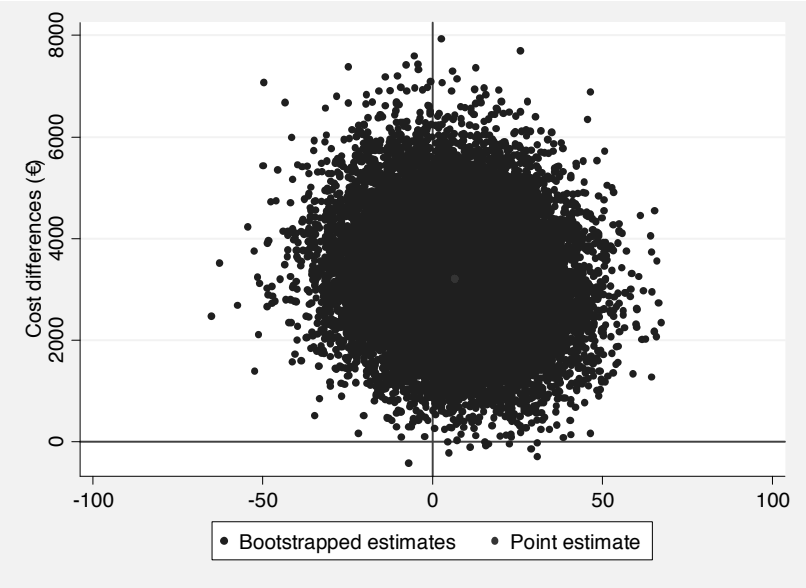

Figure 2 CE-plane for duration until sustainable RTW. *CE-plane indicating the uncertainty around the ICER for duration until sustainable RTW (societal perspective)*

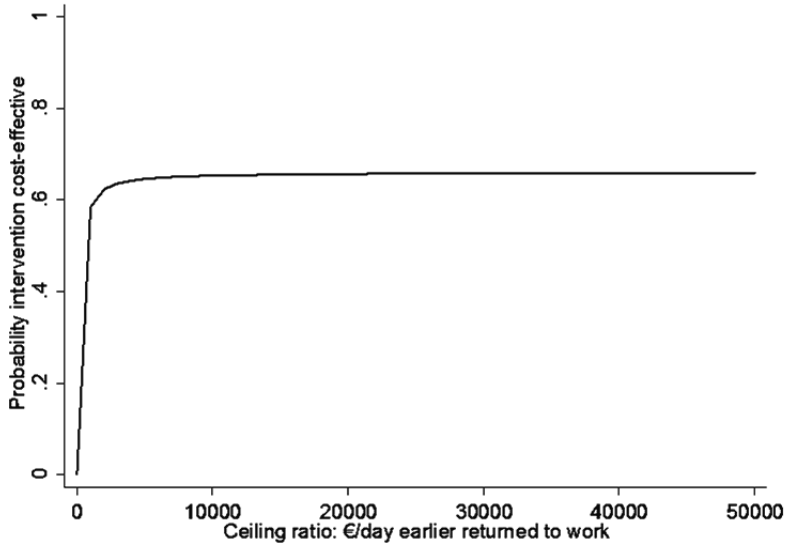

Figure 3 CEAC for duration until sustainable RTW. *CEAC indicating the probability of the intervention being cost-effective at different values (€) of willingness to pay per day earlier sustainable RTW (societal perspective)*

Cost-utility

For QALYs, an ICER of -€125 357 was found, indicating that a QALY lost was associated with a societal cost of €125 357. This relatively large negative ICER was the result of a very small difference in QALYs gained between the intervention and control group. The majority of incremental CE-pairs (50.9%) was located in the northwest quadrant of the CE-plane (Table *A3*, Figure 4), indicating that the intervention was on average more costly and less effective. A relatively large level of uncertainty around the cost-utility estimate was visible. Figure 5 illustrates that regardless of the willingness to pay, the maximum probability of the new program being cost-effective compared with usual OHC was about 0.27.

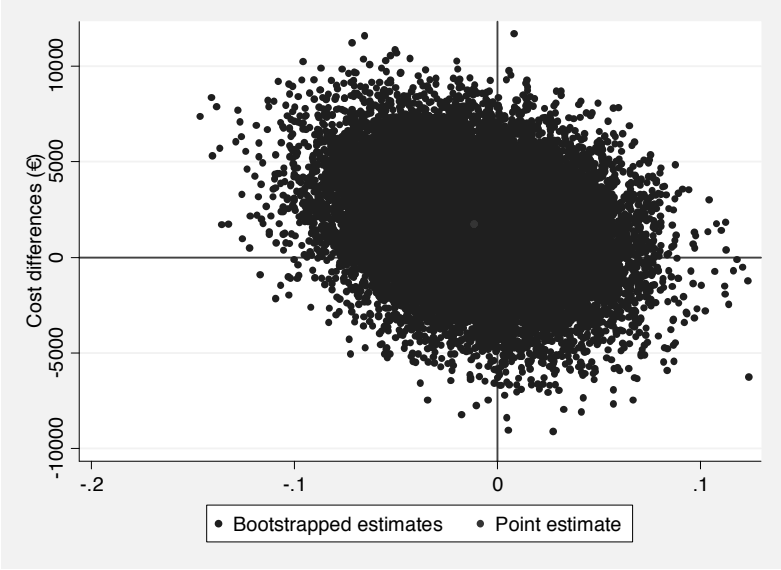

Figure 4 CE-plane for QALYs gained. *CE-plane indicating the uncertainty around the ICER for QALYs gained (societal perspective)*

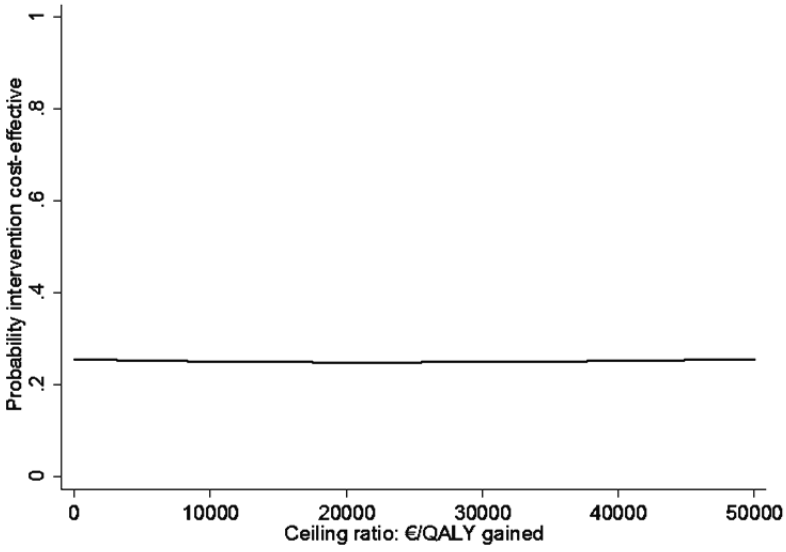

Figure 5 CEAC for QALYs gained. *CEAC indicating the probability of the intervention being cost-effective at different values (€) of willingness to pay per QALY gained (societal perspective)*

Social insurer's perspective

Financial return

Additional file 4 (Table *A4*, Appendix) presents the results of the ROI analysis. The total benefits from the social insurer's perspective were on average -€784 (95% CI €-3589–€1819), indicating higher costs for sickness benefit and employment benefit payment in the intervention group compared with the control group. The NB was on average -€1224 (95% CI -€4048–€1503), suggesting a net loss for the SSA of €1224 per intervention group participant. The BCR was -€1.80 (95% CI -€9.60–€6.50), which suggests that each Euro invested in the participatory supportive RTW program resulted in a loss of €1.80. The ROI was -278% (95% CI -1058–548), indicating a loss of 278% per Euro invested. None of these estimates was statistically significant. The estimated maximum probability of financial return was 0.18, indicating a low probability of a positive return on investment.

Sensitivity analyses

Results of SA2, SA4 and SA5 were similar to those of the main analyses, whereas the outcomes of SA1 and SA3 differed in some aspects from those of the main analyses or contained useful additional information (Table *A3*). In SA1 (complete-case analyses), the average difference in total societal costs (excluding absenteeism costs) between both groups was no longer statistically significant. In SA3 (per-protocol analyses), from the societal perspective a (not statistically significant) longer duration until sustainable RTW was found in the per-protocol group (N=36) compared with the control group, whereas in the main analysis a (not statistically significant) shorter duration was found for the intervention group. Despite these differences, all sensitivity analyses revealed a low probability of cost-effectiveness or financial return, which is in accordance with the main analyses.

Discussion

This study evaluated the cost-effectiveness, cost-utility, and ROI of a participatory supportive RTW program aimed at shortening the duration until sustainable RTW of workers without an employment contract, sick-listed due to a CMD, compared with usual OHC. From a societal perspective, the program had no significant effect on the duration

until sustainable RTW and QALYs gained. Intervention costs and medical costs were significantly higher in the intervention group, resulting in significantly higher total societal costs. The probability of cost-effectiveness for both outcomes was relatively low (ie, a maximum probability of cost-effectiveness of 0.64 for the duration until sustainable RTW at a willingness to pay of about €10 000 per day, and a maximum probability of cost-effectiveness of 0.27 for QALYs gained regardless of the willingness to pay). Furthermore, from the social insurer's perspective there was a low probability of financial return. As such, the present study does not provide evidence to implement this program in the Dutch social security sector for economic reasons.

Comparison with other studies

Over the past two decades, several economic evaluations of similar participatory RTW programs were conducted among different populations and settings [32-35]. An economic evaluation conducted in a similar setting was the study of Vermeulen et al [35]. They evaluated a participatory RTW program for temporary agency workers and unemployed workers sick-listed due to musculoskeletal disorders. Their study revealed that a societal investment of €82 was needed per one day earlier sustainable RTW, which was much lower than the ICER found in the present study (ie, €487/day). Furthermore, high probabilities of cost-effectiveness at a low willingness to pay were found in economic evaluations of a participatory RTW program for employees with low back pain [32,33]. More in line with our findings were the results from an economic evaluation of a participatory RTW program for employees with distress by van Oostrom et al [34]. They found a low probability of the program being cost-effective in reducing time to sustainable RTW compared with usual care, from the societal perspective. However, for a subgroup of their population with the baseline intention to return to work despite symptoms, the intervention was on average more effective and less costly than usual care. Both the studies of Vermeulen et al [35] and van Oostrom et al [34] revealed a low probability of the intervention being cost-effective in terms of QALYs, as was also seen in the present study.

Differences between findings from the present study and the aforementioned studies could be related to differences in effectiveness of the interventions, which have been discussed in more detail in our effectiveness evaluation [7]. Also the large role of implementation failure in the effectiveness of the participatory supportive RTW program, such as the very low

number of intervention group participants that had actually started in the participatory supportive RTW program (N=36) and the low protocol adherence within this "per-protocol group", has been discussed in our effectiveness evaluation [7]. The present study, however, provides important new insights into related costs. In the present study the mean costs for applied OHC were highest in the intervention group, but still lower than costs for applied OHC for the intervention group in the study by Vermeulen et al [35]. These higher costs in the study of Vermeulen et al seem to be (partly) related to the additional costs needed to realize an early RTW, ie, costs for rewarding a commercially operating vocational rehabilitation agency, which had been more successful in their study (19 versus nine job placements) [36,37]. Furthermore, in the present study mean secondary care costs were significantly higher in the intervention group compared to the control group, while in the study of Vermeulen et al [35] mean secondary care costs were highest in the control group. However, the higher secondary care costs for the intervention group were in line with the findings of Van Oostrom et al [34]. A post-hoc analysis following our study indicated that in the intervention group during follow-up more participants reported that they had received specialized mental healthcare (N=47; 50%) compared with the control group (N=37; 40.2%), ie, consultations at an institute for specialized mental healthcare, treatment by a psychologist/psychiatrists/psychotherapist, or (part-time) day care for mental health complaints, although differences were not statistically significant and data was not complete for all participants.

Study implications

Although the findings from our post-hoc analysis should be interpreted with caution, these findings may partly explain the association between allocation to the new participatory supportive RTW program and higher secondary care costs. An early focus on RTW may have placed high demands on both participants and professionals involved, as the most common approach for sick-listed workers with mental health problems is still to "train-and-place" in (sheltered or volunteer) work [1]. Possibly, the prospect of RTW in a competitive job and no longer being entitled to OHC and sickness benefit payment may have increased feelings of insecurity and stress in these participants. Results of our previous qualitative evaluation on the execution of the program in practice also showed that many stakeholders expressed their doubts on the feasibility of this early focus on RTW, and suggested that

often an increase of empowerment or mental resilience was first needed [38]. This means that the need for specialized (mental) healthcare possibly became more prominent. Therefore, it may be worthwhile to consider a more intensive and ongoing support by a multidisciplinary team of professionals from the SSA, the (mental) healthcare sector, and from a vocational rehabilitation agency, and a more simultaneously focus on treatment and vocational needs. From an economic perspective, further research is necessary to investigate whether such an approach could reduce secondary care costs without increasing intervention costs.

In addition, for any future intervention for sick-listed workers without an employment contract, it is important to consider how costs needed to realize an early RTW in the absence of a job to return to can remain low. In this regard, Vermeulen et al [35] proposed several measures, such as realizing subsidized workplaces, increasing responsibilities of employers with regard to facilitation of RTW, and creating a network of potential workplaces. Very recently in the Netherlands, application of a no risk policy for (ex) cancer patients without an employment contract was considered. This policy compensates employers for sickness absence costs, in order to create an incentive for employers to hire particularly these workers [39]. Future research is needed to assess whether such measures may also contribute to a cost-effective RTW program for workers without an employment contract, sick-listed due to a CMD.

Strengths and limitations

This study provides insight into the costs of the participatory supportive RTW program in relation to its effects. Although the program showed no beneficial or adverse effect on the duration until sustainable RTW, information about its associated costs is needed to determine its probability of cost-effectiveness and financial return. Moreover, reporting the probability of cost-effectiveness and financial return of this program contributes to unbiased systematic reviews on the resource implications of these kind of interventions.

Another strength concerns the use of state-of-the-art statistical measures, ie, the use of multiple imputations, SUR analyses and bootstrapping. This was one of the first studies in which bootstrapping techniques were not only used to estimate 95% CIs surrounding skewed cost data, but also to estimate the level of uncertainty around NB, BCR and ROI

estimates, as well as the probability of financial return, which is very useful for decision-makers in OHC.

A third strength is the study's pragmatic RCT design, which made it possible to conduct an economic evaluation in the "real-life" setting. A disadvantage of this design is that caution is needed when generalizing the results of this study to another jurisdiction.

A fourth strength concerns the use of registered data by the SSA. Herewith, possible bias caused by self-report, such as recall bias, was minimized. Furthermore, data on RTW, applied OHC and paid benefits by the SSA could be obtained for all participants. Consequently, only five imputed datasets were needed to conduct the analyses. Nevertheless, due to missing self-reported data on QALYs and medical costs, data was complete for only 46% of participants. We dealt with this limitation by using multiple imputations.

Another limitation of this study may be the assessment of medication use. The self-reported data on medication use were often difficult to interpret, as medication names were misspelled or the brand name was used. To limit bias, we chose to only consider the use of psychotropics as these were easy to recognize, and the use of these medications was most likely to be affected by the intervention under study.

A third limitation was that presenteeism during work resumption was not taken into account, although presenteeism costs can be high. However, a sophisticated method for estimating and valuing presenteeism does currently not exist and therefore only a crude estimate of presenteeism costs could have been provided.

For our estimation of productivity loss we did not take into account hours worked in unpaid employment, which was a fourth limitation. This may have led to an overestimation of the actual productivity loss in both groups. However, only self-reported information about work resumption in unpaid labor was available and this was often incomplete. Therefore, the number of hours worked in unpaid employment could not be assessed properly. Moreover, because sick-listed workers without an employment contract are more often low-skilled and have less work experience compared to sick-listed employees [40], they may also be less productive compared to other employees. Therefore, the estimated price of productivity loss for a Dutch worker per hour, based on sex and age that was used to value productivity loss, possibly also resulted in an overestimation of productivity loss.

Nevertheless, because an overestimation of productivity loss probably took place in both groups, we were still able to compare productivity loss between these groups.

Finally, a very large number of sick-listed workers was sent an invitation for participation in this study (N=9822) to reach those sick-listed workers with mental health problems, because it was not possible to select potential participants based on a registered mental health problem. This recruitment procedure could be considered as a limitation of this study. We do not know how many sick-listed workers of those who did not respond to the questionnaire (N=8058) actually were sick-listed due to a CMD. Still, we can assume that among this group there were sick-listed workers who actually would have met the criteria for eligibility. The large number of non-responders and the large number of sick-listed workers who responded to the invitation but were not willing to participate (N=941), indicate that selection bias may have played a role. Possibly, sick-listed workers who participated in this study were more willing to (actively) participate in the new program, compared to the ones who did not. The possibility of selection bias could further complicate generalizing the results of this study to other settings, and is therefore an important limitation.

Conclusions

The participatory supportive RTW program was neither cost-effective in improving sustainable RTW nor in gaining QALYs from the societal perspective. Also, from the perspective of the SSA, the program did not result in a positive financial return. Based on the results of this study, we cannot recommend implementing the participatory supportive RTW program in the Dutch social security sector.

Appendix

Table A1 Baseline characteristics

Baseline characteristics	Intervention group			Control group		
	All (N=94)	Complete (N=42)	Incomplete (N=52)	All (N=92)	Complete (N=44)	Incomplete (N=48)
Demographic characteristics						
Gender, N (%) Female	45 (48%)	21 (49%)	24 (47%)	47 (51%)	23 (51%)	24 (51%)
Age in years, mean (SD)	45.7 (10.6)	46.8 (9.9)	44.8 (11.2)	46.3 (10.0)	49.0 (9.3)	43.6 (10.0)
Education, N (%) Low [a]	26 (28%)	11 (26%)	15 (29%)	23 (25%)	13 (29%)	10 (21%)
Work status						
Employment contract at baseline, N (%) Yes	11 (12%)	6 (14%)	5 (10%)	14 (15%)	2 (4%)	12 (26%)
Type of worker before reporting sick						
N (%) unemployed	88 (94%)	40 (93%)	48 (94%)	85 (92%)	44 (98%)	41 (87%)
N (%) temporary agency worker	4 (4%)	1 (2%)	3 (6%)	2 (2%)	0 (0%)	2 (4%)
N (%) fixed-term contract worker	2 (2%)	2 (5%)	0 (0%)	5 (5%)	1 (2%)	4 (9%)
Work schedule in last job, N (%) day work	72 (77%)	31 (72%)	41 (80%)	75 (82%)	38 (84%)	37 (79%)
Working hours per week in last job, mean (SD)	32.6 (11.6)	32.0 (10.8)	33.0 (12.3)	31.4 (10.8)	31.5 (9.8)	31.2 (11.8)
Years worked in last job, mean (SD)	10.0 (10.0)	11.0 (10.9)	9.1 (9.2)	8.7 (9.6)	8.7 (9.8)	8.6 (9.5)
***Expectation regarding ability for full RTW in 6 months**, N (%) (very) certain **ASE**, mean (SD):* [b]	4 (4%)	1 (2%)	3 (6%)	16 (17%)	8 (18%)	8 (17%)
Attitude (6-30 score)	15.7 (5.2)	15.2 (4.4)	16.0 (5.9)	14.9 (4.2)	14.1 (3.8)	15.8 (4.4)
Normative beliefs (4-20 score)	12.0 (3.1)	11.7 (2.9)	12.3 (3.3)	12.6 (2.6)	12.6 (2.1)	12.6 (3.0)
Social modelling (2-10 score)	4.8 (1.9)	4.6 (1.4)	5.0 (2.2)	4.8 (1.5)	4.9 (1.4)	4.7 (1.7)
Self-efficacy (2-10 score)	6.3 (1.8)	6.0 (1.4)	6.6 (2.1)	6.2 (1.6)	6.2 (1.6)	6.3 (1.6)
Intention to RTW, N (%) Yes	78 (83%)	39 (91%)	39 (77%)	81 (88%)	42 (93%)	39 (83%)
***Fear avoidance beliefs** (4-40 score), mean (SD)* [c]	29.0 (6.9)	29.1 (6.7)	28.8 (7.0)	28.5 (7.0)	28.9 (6.4)	28.2 (7.7)

N=Number; SD=Standard deviation

[a] Low educational level included no education, primary school or lower vocational education

[b] A lower score on these scales corresponds with a more positive attitude regarding RTW (attitude), a stronger belief that other people think work resumption is important (normative beliefs), finding it more important what other people think (social modelling) and a stronger feeling of self-efficacy regarding RTW (self-efficacy)

[c] A higher score on this scale, indicates a stronger belief that health complaints could interfere with RTW

Table A2 Mean costs per participant in the intervention and control group and crude and adjusted cost differences between both groups during follow-up

Cost category	Intervention N=94; mean (SEM)	Control N=92; mean (SEM)	Mean cost difference Model 1[a] (95%CI)	Mean cost difference Model 2[b] (95%CI)
Intervention costs	1130 (108)	623 (84)	507 (252–789)	440 (143–734)
OHC consults	420 (36)	305 (22)	114 (39–205)	135 (57–255)
Additional support	557 (101)	318 (77)	239 (-1–507)	151 (-111–418)
Training costs	153 (NA)	0 (NA)	153 (NA)	153 (NA)
Medical costs	6323 (946)	3452 (486)	2871 (1073–5147)	2765 (918–4876)
Primary care	1858 (199)	1649 (185)	210 (-251–648)	179 (-277–675)
Secondary care	4432 (875)	1769 (432)	2662 (1007–4740)	2587 (879–4510)
Medication	34 (5)	34 (5)	-1 (-14–12)	-2 (-15–11)
Absenteeism costs	44413 (1801)	44981 (1736)	-569 (-5185–4472)	-549 (-5185–4472)
Total societal costs	*51866 (2076)*	*49057 (1884)*	*2809 (-2451–8385)*	*1712 (-3520–6650)*
Total societal costs excluding absenteeism costs	*7453 (956)*	*4075 (496)*	*3378 (1557–5670)*	*3206 (1346–5337)*

N=number; 95% CI=95% Confidence Interval; SEM=Standard Error of the Mean; NA=Not applicable

[a] Not corrected for confounders

[b] Corrected for baseline differences in demographic characteristics + type of worker + RTW expectation + ASE + intention to RTW + fear avoidance beliefs

Table A3 Differences in pooled mean costs and effects (95% CIs), ICERs, and the distribution of incremental CE-pairs around the quadrants of the CE-planes (societal perspective)

Analysis	Sample size (N)		Effect measures	ΔC (95% CI)	ΔE (95%CI)	ICER	Distribution CE-plane (%)			
	Intervention	Control		€	Points	€/point	NE[1]	SE[2]	SW[3]	NW[4]
Main analysis *– Imputed dataset*	94	92	Duration to sustainable RTW (days)	3206 (1346–5337)	-6.6 (-37.8–24.6)	-487	67.3	0.0	0.0	32.7
	94	92	QALY	1712 (-3520–6650)	-0.01 (-0.08–0.06)	-125357	28.9	12.4	12.8	50.9
SA1 *– Complete-case analysis*	42	44	Duration to sustainable RTW (days)	2261 (-500–6028)	-17 (-56 to 21)	-129	77.3	6.5	1.2	15.0
	42	44	QALY	97 (-7195–6817)	0.07 (-0.02–0.16)	1377	45.9	47.2	2.3	4.5
SA2 *– Excluding healthcare outliers*	89	90	Duration to sustainable RTW (days)	2657 (1195–4537)	-3.6 (-36–28)	-598	59.9	0.0	0.0	40.1
	89	90	QALY	1762 (-3364–6821)	-0.02 (-0.09–0.05)	-76267	19.3	9.8	15.1	55.8
SA3 *– Per-protocol*	36	92	Duration to sustainable RTW (days)	3355 (723–6403)	3.1 (-40.5–46.7)	820	41.5	0.9	0.6	57.0
	36	92	QALY	3798 (-4126–10973)	0.01 (-0.07–0.09)	686302	45.5	12.4	3.8	38.4
SA4 *– FCA; 23 weeks*	94	92	QALY	2606 (98–5317)	-0.01 (-0.08–0.06)	-215336	35.0	1.3	1.1	62.7
SA5 *– FCA; 12 weeks*	94	92	QALY	3160 (1145–5381)	-0.01 (-0.08–0.06)	-269932	36.1	0.0	0.0	63.7

N=Number; C=Costs; E=Effects; ICER=Incremental Cost-Effectiveness Ratio; CE-plane=Cost-Effectiveness-plane; QALYs=Quality-adjusted Life Years
Note: cost and effect differences were corrected for baseline differences in demographic characteristics + type of worker + RTW expectation + ASE + intention to RTW + fear avoidance beliefs
[1] Refers to the northeast quadrant of the CE-plane, indicating that the intervention is more effective and more costly usual care
[2] Refers to the southeast quadrant of the CE-plane, indicating that the intervention is more effective and less costly than usual care
[3] Refers to the southwest quadrant of the CE-plane, indicating that the intervention is less effective and less costly than usual care
[4] Refers to the northwest quadrant of the CE-plane, indicating that the intervention is less effective and more costly than usual care

Table A4 Intervention costs, benefits, NBs, BCRs, and ROIs per participant (social insurer's perspective)

Analysis	Sample size (N)		Costs	Benefits	Financial return			
	Intervention	Control	Total (95% CI)	Total (95% CI)	NB[1] (95% CI)	BCR[2] (95% CI)	ROI (%)[3] (95% CI)	Probability
Main analysis	94	92	440 (143–734)	-784 (-3589–1819)	-1224 (-4084–1503)	-1.8 (-9.6–6.5)	-278 (-1058–548)	0.18
Imputed dataset								
SA1	92	90	423 (128–737)	-920 (-3755–1846)	-1343 (-4262–1527)	-2.2 (-10.9–6.7)	-317 (-1191–569)	0.17
Complete-case analysis								
SA2	89	90	432 (119–730)	-1032 (-3766–1865)	-1464 (-4357–1393)	-2.4 (-10.9–5.7)	-339 (-1190–469)	0.16
Excluding healthcare outliers								
SA3	36	92	1121 (700–1554)	-1654 (-5003–1560)	-2775 (-6229–606)	-1.4 (-4.5–1.6)	-248 (-553–63)	0.05
Per-protocol								

N=number; 95% CI=95% Confidence Interval; NB=Net Benefit; BCR=Benefit Cost Ratio; ROI=Return-On-Investment

Note1: Costs and benefits were corrected for baseline differences in demographic characteristics + type of worker + RTW expectation + ASE + intention to RTW + fear avoidance beliefs

Note2: Financial returns are positive if the following criteria are met: NB>0, BCR>1, and ROI>0

[1] Indicates the amount of money returned after intervention costs are recovered

[2] Indicates the amount of money returned per Euro invested in the intervention

[3] Indicates the percentage of profit per Euro invested in the intervention

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8

General discussion

Sick-listed workers without an employment contract seem to have a more vulnerable position in the labor market compared to sick-listed employees [1,2]. Mental disorders are the most frequently diagnosed disorders within this group [2]. Nevertheless, evidence-based return to work (RTW) interventions aimed at these vulnerable workers are lacking [3]. The main aim of this thesis was to improve RTW of workers without an employment contract, sick-listed due to a common mental disorder (CMD). The sub objectives of this thesis were: 1. to get a broad understanding of factors that in the long run influence sustainable RTW of sick-listed workers with a CMD; 2. to develop a new participatory supportive RTW program for workers without an employment contract, sick-listed due to a CMD, based on a participatory RTW program, integrated care and direct placement in a competitive job; 3. to evaluate the execution of this new program in practice; and 4. to evaluate its effectiveness and cost-effectiveness in shortening the duration until sustainable RTW in a competitive job. To reach our first aim we studied associations between biopsychosocial factors and sustainable RTW of sick-listed workers with a depressive and/or anxiety disorder, by using data of a large Dutch cohort study (ie, "The Netherlands Study of Depression and Anxiety") [4]. To reach our other aims, we carried out a randomized controlled trial (RCT) titled "The Co-WORK study", in which we compared the new participatory supportive RTW program with usual occupational healthcare (OHC) for Dutch sick-listed workers without an employment contract.

This chapter will start with a summary of our main findings, followed by a comparison with findings from other studies. Subsequently, challenges in improving RTW of workers without an employment contract sick-listed due to a CMD will be discussed. Thereafter, we will discuss the type of potential pitfalls of this thesis and methodological considerations. Finally, we will present implications of our findings for research and practice.

Main findings

Our study on longitudinal associations between biopsychosocial factors and sustainable RTW of sick-listed workers with a depressive and/or anxiety disorder showed that in the long run non-disorder-related factors, ie, the presence or absence of an employment contract, age and income, are more likely to influence sustainable RTW compared to disorder-related factors. These results reveal that it is insufficient to solely focus on

disorder-related factors, when one's aim is to improve RTW of sick-listed workers with a CMD. Further, these results illustrate that some workers, such as workers without an employment contract, are more vulnerable than others when becoming sick-listed (chapter 2).

To shorten the duration until sustainable RTW of a vulnerable group of sick-listed workers with a CMD, ie, workers without an employment contract, we developed a new RTW program. The core of this participatory supportive RTW program consisted of a participatory approach aiming to identify and solve the main biopsychosocial obstacles for RTW in a stepwise process, in which the sick-listed worker actively participates together with a supervisor. Direct placement in a competitive job by a vocational rehabilitation agency was incorporated in the new program to overcome the most important obstacle for RTW of these workers, ie, the absence of a workplace to return to. An integrated care approach was added to the program to stimulate cooperation between professionals of the Dutch Social Security Agency (SSA) – responsible for OHC of these sick-listed workers – and other healthcare professionals, and to avoid conflicting advice about RTW (chapter 3).

However, in comparison with usual OHC for workers without an employment contract with a CMD, the new program did not result in a (cost-effective) improvement in the duration until sustainable RTW of these workers. The (adjusted) Hazard Ratio (HR) of the intervention group compared to the control group was 1.15 (95% CI 0.61–2.16). Also no significant differences were found in favor of the intervention group on any secondary outcome, ie, average working hours, duration until RTW in any type of employment, sickness benefit duration, and perceived physical and mental health and functioning. Furthermore, intervention costs and medical costs were significantly higher in the intervention group compared to the control group. From a societal perspective, the maximum probability of cost-effectiveness was 0.64 at a willingness to pay of about €10 000 for one day earlier sustainable RTW. From the social insurer's perspective intervention costs were significantly higher and benefits were lower, resulting in a low probability of financial return. "Per-protocol analyses", including only those intervention group participants who actually participated in the new program (N=36), also revealed higher costs in the intervention group and no significant effects compared to the control group (chapter 6 and 7).

Nevertheless, due to low protocol adherence it remains unclear what the results would have been if the program had been executed according to protocol. Our evaluation of the execution of the new program in practice revealed that also in the "per-protocol group" (N=36) adherence to the protocol was low to reasonable. Overall, some steps of the program were not executed (timely). Especially the last step of the program, consisting of placement in a suitable competitive job by a vocational rehabilitation agency, did not have the intended result. An important barrier for a successful execution of this component, perceived by the stakeholders in our study, was a limited availability of suitable workplaces in the Dutch labor market. Stakeholder perceptions also revealed a poor collaboration between the Dutch SSA, the vocational rehabilitation agencies and the mental healthcare sector. This explains why the step between the making of a RTW action plan and job hunting by a vocational rehabilitation agency on the basis of this action plan was sometimes considered problematic, and why an integrated care approach was not always executed according to protocol. Other perceived barriers for a successful execution of the program were related to the type of (health) problems experienced by the clients, and to time constraints for the professionals who participated in the new program. Still, application of a participatory approach was quite positively evaluated by the stakeholders (chapter 4 and 5).

Comparison with other studies

Studies on prognostic factors for return to work

A systematic review by Cornelius et al [5] revealed that disability and RTW of sick-listed workers with mental health problems are for a large part influenced by non-disorder-related factors, such as personal and work-related factors. This is in line with the results of our study on longitudinal associations between biopsychosocial factors and sustainable RTW of sick-listed workers with a depressive or anxiety disorder (chapter 2). Audhoe et al [6] studied associations between biopsychosocial factors and work participation specifically in workers without an employment contract, sick-listed due to mental health problems, who are also the target population of this thesis. Their study also revealed that non-disorder-related factors seem to be important in predicting RTW. They identified perceived moderate or good health, a younger age, positive expectations of a full RTW, and still being (part-time) employed as strong prognostic factors for work participation in the long run [6].

Some of the modifiable factors identified in these prognostic studies, were particularly addressed in the participatory supportive RTW program evaluated in this thesis. To illustrate, vocational rehabilitation agencies were contracted in order to facilitate RTW. Furthermore, the program was designed to address all relevant biopsychosocial obstacles for RTW.

Studies on a participatory return to work program

Multiple studies have demonstrated a beneficial effect of a participatory RTW program on the duration until (sustainable) RTW of sick-listed employees with low back pain [7-9]. A study of Vermeulen et al [10] showed that this approach could also reduce the duration until sustainable RTW for sick-listed workers without an employment contract, ie, temporary agency workers and unemployed workers sick-listed due to a musculoskeletal disorder. The program evaluated in the study of Vermeulen et al was very similar to the program that was evaluated in this thesis. However, in the study of Vermeulen et al participants were placed in a (therapeutic) workplace with ongoing benefits from the SSA, whereas in our study only direct placement in a competitive (paid) job was considered suitable (with a maximum continuation of the sickness benefit payment of three months).

The beneficial effect of a participatory RTW program reported for sick-listed workers with physical complaints was found neither for the target population of this thesis (chapter 6) nor for sick-listed employees with a CMD [11]. This suggests a discrepancy in the effectiveness of a participatory RTW program between sick-listed workers with physical and mental health complaints. A review of workplace interventions by Van Vilsteren et al [12] reported a comparable discrepancy, ie, workplace interventions were found to improve RTW in workers with musculoskeletal disorders and no such evidence was found for workers with mental health problems. In addition, a systematic review of intervention characteristics that facilitate RTW after sickness absence by Hoefsmit et al [13] revealed that some facilitating intervention characteristics were particularly effective for sick-listed workers with physical complaints.

When comparing the cost-effectiveness of the participatory RTW programs evaluated in the aforementioned studies, we also see a higher probability of the program being cost-effective in reducing the duration until sustainable RTW in those studies focusing on workers with

physical complaints [14-17], compared to the study of Van Oostrom et al [18] concerning sick-listed employees with a CMD, and the findings of this thesis (chapter 7).
Nevertheless, Van Oostrom et al found a beneficial intervention effect and a higher probability of financial return for a subgroup of their population who at baseline intended to RTW, despite ongoing health complaints [11,18]. The selection of participants in the Co-WORK study was based on such a positive intention to RTW, and we adjusted our analyses for possible changes in this intention between selection and baseline. However, an important difference between participants in our study and the subgroup in the study of Van Oostrom et al was that participants in our study had no (longer a) workplace to return to. Differences in results between these two studies suggest a difference in effectiveness of a participatory RTW program between those workers with a CMD who are still employed and those who have no (longer an) employment contract.

Studies on return to work programs for workers without an employment contract, sick-listed due to a common mental disorder
Studies aiming to improve RTW of sick-listed workers with a CMD who have no employment contract are very limited [3]. However, recently another Dutch study on a RTW program for workers without an employment contract sick-listed due to mental health problems was conducted. This study by Audhoe et al [19] also revealed no beneficial intervention effect, compared to usual OHC. Their explanations for this lack of effect were low protocol adherence of the participating professionals of the Dutch SSA and unsuccessful counseling by contracted vocational rehabilitation agencies. Comparable factors were seen in our study (chapter 4 and 5).

Challenges in improving return to work of workers without an employment contract, sick-listed due to a common mental disorder

The findings of this thesis and the comparison of these findings with existing literature, reveal several challenges in improving RTW of workers without an employment contract, sick-listed due to a CMD. The Attitude-Social influence-self-Efficacy (ASE) model can be used to explain these challenges. Return to work can be considered as a complex behavioral change [20]. The ASE model suggests that behavioral change is determined by attitudes,

social influence and self-efficacy regarding this behavior, with the intention to change as a mediating factor [21-23]. The ASE model further assumes that the step between the intention to change a certain behavior and actual behavioral change can be impeded or facilitated by environmental characteristics, and is also dependent on the knowledge and skills needed to change this behavior [22,23]. The model was previously used to explain whether someone returns to work or not in studies by Van Oostrom et al [22] and Vermeulen et al [23]. Furthermore, a study of Brouwer et al [24] on behavioral determinants as predictors of RTW provided evidence for an association between the ASE determinants and the duration until RTW.

In the applied ASE model attitude towards RTW concerns the individual weighing of the perceived advantages and disadvantages of RTW, which results from beliefs, preferences, motivation and expectations regarding (time to) RTW. Social influence is the perception of what significant others think about RTW and the feedback of such significant others, eg, social support or peer pressure. Self-efficacy is the individual's confidence in his/her ability to return to work, which may result from feelings of control, expectation regarding the feasibility of RTW and the attribution of complaints/barriers and solutions [21-23]. Barriers and facilitators that influence the relation between the intention to return to work and actual RTW may stem from all the systems involved in the societal context, ie, the workplace system, healthcare system, personal system and wage compensation system [25]. The applied ASE model is illustrated in Figure 1.

Based on our findings, we distinguish four challenges to improve RTW of workers without an employment contract, sick-listed due to a CMD:

1. the absence of a workplace/employer;
2. perceived ill-health and inability to return to work early after sick-listing;
3. poor collaboration between services in (occupational) healthcare and vocational rehabilitation;
4. constraints in time or capacity within the organizations involved.

On the next page, we use the ASE model to further explain why these factors can be considered important challenges.

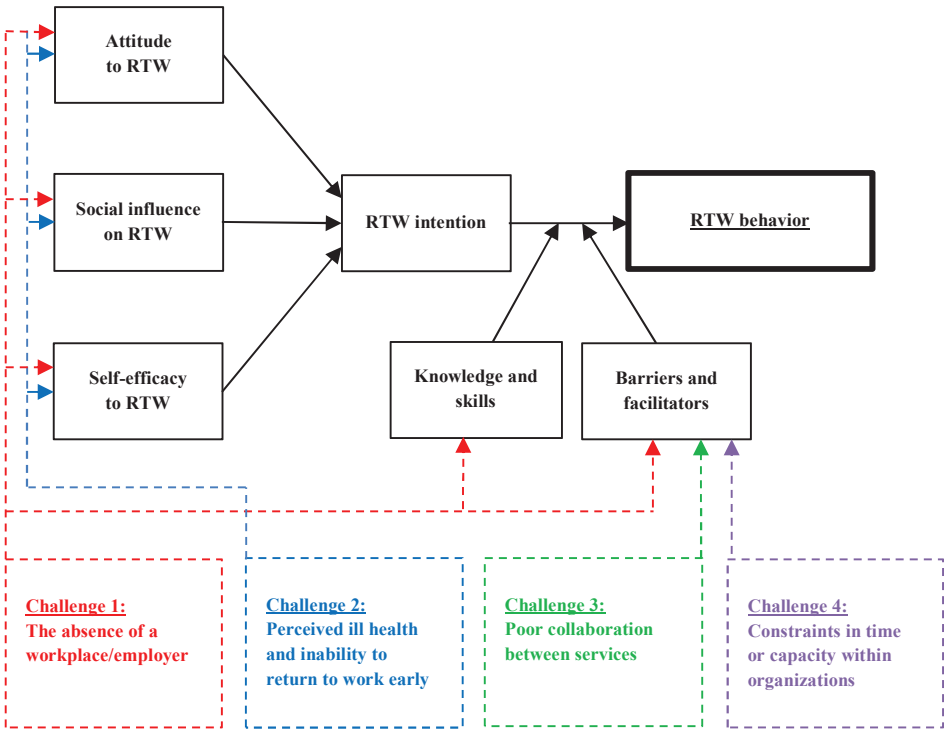

Figure 1 Applied ASE model to explain challenges in improving RTW of workers without an employment contract, sick-listed due to a CMD

1. The absence of a workplace/employer

The absence of a workplace to return to seems to complicate RTW of sick-listed workers without an employment contract to a large extent [1,2]. Firstly, the absence of a clear RTW perspective may influence the self-efficacy of these workers towards RTW. Our evaluation of the execution of the new participatory supportive RTW program in practice indicated that in the absence of this perspective, it is challenging to translate experienced mental health problems into concrete obstacles for RTW and to find practical solutions to overcome these obstacles (chapter 4 and 5).

Secondly, the absence of a workplace complicates the step between the intention to return to work and actual RTW. Actual RTW for these workers becomes dependent on the availability of suitable jobs in the labor market, and the willingness of employers to hire this particular worker. Compared to sick-listed employees, sick-listed workers without an

employment contract often have less education or work experience [1,2]. Therefore, it is difficult to compete with other job seekers. According to the sick-listed workers and professionals who participated in the new program, these less favorable characteristics and the limited labor market opportunities at the time the study was conducted – ie, during an economic recession – were important barriers for placement in a suitable competitive job (chapter 5).

Thirdly, the absence of a workplace to return to can also become a challenge when, because of the provision of supportive income, the sick-listed worker experiences a so-called "benefit trap" (chapter 2). The sick-listed worker might find himself/herself unable to get a job that pays more than this supportive income, or is afraid that this benefit will no longer be paid when he/she becomes sick-listed again. Such a benefit trap can be a disincentive to return to work [26]. As the main focus of the new program was on RTW in a competitive job without ongoing benefits, it is possible that a benefit trap was perceived by some of the participants in this program. This shows that the absence of a workplace to return to can influence the attitude of sick-listed workers regarding RTW.

Finally, workers without an employment contract may experience less social support in their RTW process. Van Vilsteren et al [27] found that a participatory RTW intervention aimed at employees with rheumatoid arthritis had a positive effect on the support these employees experienced from their supervisor at the workplace. This supervisor support was considered essential in the implementation of solutions to overcome RTW obstacles at the workplace [27]. In an earlier study, Tamminga et al [28] identified experienced supervisor support as a key factor in the RTW process of employed breast cancer survivors. For workers without an employment contract, this kind of support is lacking.

2. Perceived ill-health and perceived inability to return to work early after sick-listing

Perceived ill-health and perceived inability to return to work early after sick-listing also seem to influence RTW of workers without an employment contract, sick-listed due to a CMD in multiple ways. Firstly, the more negative attitude of these sick-listed workers towards their health status seems to affect their RTW process. Several studies reveal an association between perceived health and RTW of workers without an employment contract [6,29,30]. We used the 4-Dimensional Symptom Questionnaire (4DSQ) [31] and the Dutch translation of the SF-36 [32] to assess perceived health among participants in the Co-

WORK study (chapter 6). These scores revealed that, especially at baseline, perceived health among the participants in our study was much worse compared to norm scores of the SF-36 [32,33], and compared to scores on the 4DSQ in the aforementioned study among sick-listed employees with a CMD [11]. This is in line with findings of two Dutch studies [1,2], that showed a worse health perception of sick-listed workers without an employment contract compared to sick-listed employees. Both studies indicated that personal circumstances, such as financial or relational problems, often play an important role in the health perception of workers without an employment contract [1,2]. This illustrates that the evaluation of their own health may be negatively affected by factors in their personal environment.

Secondly, in line with their ill-health perception, workers without an employment contract, sick-listed due to a CMD, may not always feel confident to RTW. This means that feelings of self-efficacy are challenged. Participants in the new program stressed that they were sometimes insecure about their ability to return to work (chapter 5). This may be a reflection of fear-avoidance beliefs, which is related to subjective health complaints and negative illness perceptions [34]. In addition, also anticipated stigma may have played a role. A study of Brouwers et al [35] showed that anticipated stigma is highly prevalent among people with a depressive disorder. Both fear-avoidance beliefs and anticipated stigma are important risk factors for not returning to work [34,35].

Finally, a negative perception of these sick-listed workers' health status and ability to return to work early after sick-listing by other stakeholders also seem to affect the RTW process of these workers, via the social influence of these stakeholders. Our qualitative evaluation of the execution of the new program in practice showed that the participating insurance physicians often thought that participation in this program could worsen mental health complaints. Therefore, a large number of eligible participants in the Co-WORK study allocated to the new program did not actually start in this program. This illustrates that, although the new program was aimed at a large group of sick-listed workers, the program was only considered suitable for a small group. Also for participants who actually participated in the new program this program was sometimes perceived too demanding by the professionals involved. Often the search for a suitable job was postponed, because of doubts about the participant's readiness for RTW. Some participating professionals thought that first an increase of their mental resilience was needed (chapter 4 and 5). The early

focus on RTW in a competitive job, without further entitlement to OHC and sickness benefit, made it necessary for the participating professionals in the Co-WORK study to consider the participant's readiness for RTW in an early phase. As a result, the health complaints that were still experienced by the participant may have received extra attention. Our economic evaluation revealed higher secondary care costs in the intervention group, which illustrates that the need for (mental) healthcare possibly became more prominent (chapter 7). However, doubts about the participants' readiness for RTW may also stem from a lesser acceptance among the stakeholders involved to start planning RTW for sick-listed workers with unresolved mental health problems [11]. This belief might be rooted in the traditional first-train-then-place approach, with the emphasis on prevocational training and placement in volunteer or sheltered work [36-38]. These findings illustrate that workers without an employment contract, sick-listed due to a CMD, may feel little support to return to work early.

3. Poor collaboration between services in (occupational) healthcare and vocational rehabilitation

An important barrier in the step between the intention to return to work and actual RTW of workers without an employment contract, sick-listed due to a CMD, is the poor collaboration between the different services involved. Several studies demonstrate the importance of an integrated care approach in improving RTW of sick-listed workers, through a strong collaboration between healthcare providers and vocational rehabilitation services [8,36,39,40]. For that reason, in the new program the insurance physician of the SSA was encouraged to contact the healthcare provider of the sick-listed worker to agree on treatment and RTW. In addition, vocational rehabilitation agencies were contracted, to facilitate the search for a suitable competitive job. However, in our evaluation of the execution of the new program this integration of services was still considered an important challenge (chapter 5). Earlier, two Dutch studies [41,42] reported that in the Netherlands communication and collaboration between professionals in the curative healthcare sector, such as general practitioners (GPs), and the vocational rehabilitation sector, such as occupational physicians, is very limited. Difficulties in the implementation of an integrated care approach were also seen in the aforementioned study of Van Vilsteren et al [43]. The Co-WORK study revealed that even a telephone contact between the insurance physician

and the sick-listed worker's healthcare provider could be difficult to accomplish. Also collaboration between professionals of the SSA and the contracted vocational rehabilitation agencies was often poor. To illustrate, case managers of the vocational rehabilitation agencies in some cases still developed a new RTW action plan instead of simply applying the action plan already developed at the SSA (chapter 5).

4. Constraints in time or capacity

Constraints in time or capacity within the organizations involved in OHC of workers without an employment contract, sick-listed due to a CMD, can also be an important barrier in the step between the intention to return to work and actual RTW of these workers. The professionals who participated in the new program indicated that due to competing priorities there had been too little time to execute the intervention properly (chapter 5). One of the consequences was less continuity in OHC than was prescribed in the protocol (chapter 4). This is an important concern, as less continuity in OHC has found to be associated with a longer duration until RTW [44,45]. In the aforementioned intervention study of Audhoe et al [19] organizational constraints at the Dutch SSA were also considered a possible explanation for the poor continuity in the execution of the intervention under study. Another possible explanation mentioned by Audhoe et al [19] was that professionals of the SSA were not used to work according to a tight protocol and therefore a behavioral change was needed, which was difficult to accomplish. Possibly, this also has played a role in our study. Because very few participants actually participated in the new program, this program was not adopted in the daily routine of the participating professionals, making it more difficult to adapt their usual behavior in accordance with the new protocol.

Visualization of challenges

To visualize the challenges explained above, we will continue our description of the two cases that were introduced in the beginning of this thesis (chapter 1). Both case descriptions illustrate several challenges.

> *After losing his job, Danny (43 years old), feels very insecure about his ability to work. Furthermore, he experiences some financial problems, causing a lot of*

stress. These feelings lead to relationship problems and eventually to a divorce from his wife. After a while, Danny feels so depressed that he decides to claim for a sickness benefit at the Dutch SSA. At the SSA he has an appointment with the insurance physician for a medical examination. Here Danny tells about his depression that has become worse after his divorce. He has been referred to a psychologist by this general practitioner, but is still awaiting his first appointment. Furthermore, Danny has to find a new place to live and still carries some financial responsibilities for his ex-wife and kids. He wishes to return to work, but faces too many obstacles. The insurance physician advises Danny to first take some time to find new housing, to adapt to his new situation, and to start with treatment for his depression. The insurance physician thinks that Danny will not be able to return to work for at least three months.

In Danny's case RTW seems to be challenged mainly by perceptions of Danny and his insurance physician regarding his health status and ability to return to work, which influences Danny's perceived self-efficacy in reaching RTW, his attitude towards RTW, and experienced support to return to work. Also barriers in his personal environment and the healthcare system play a role.

Barbara (38 years old) files a sickness benefit claim at the SSA due to anxiety complaints. Together with the RTW coordinator and labor expert of the SSA, she makes a RTW action plan. In this action plan, her main obstacles for RTW are listed, along with solutions to overcome these obstacles and suggestions for suitable work. Together they decide that Barbara should preferably return to work in an administrative job with a clear and fixed set of task descriptions, where she does not have to work together with too many people, and where she gets enough time to get used to this new routine. However, according to the case manager of a vocational rehabilitation agency she has been referred to, finding such a job is extremely difficult. Moreover, the case manager thinks that Barbara first needs some prevocational training to increase her confidence, skills and motivation.

In Barbara's case RTW seems to be challenged both by the absence of a job to return, which forms a barrier between the intention to return to work and actual RTW, and by the case manager's perception of Barbara's ability to return to work, which influences the support to return to work.

Implementation failure or theory failure?

Implementation failure may be a possible explanation for the absence of a beneficial effect of the participatory supportive RTW program, evaluated in the Co-WORK study. Firstly, a very small number of participants allocated to the new program actually participated in this program. Secondly, in case of participation in the program, adherence to the protocol was still only low to moderate. The challenges discussed above could have played a major role in this implementation failure. For example, a successful execution of the program may have been impeded by a limited availability of suitable jobs in the Dutch labor market, poor collaboration between services in (occupational) healthcare and vocational rehabilitation, and constraints in time or capacity within the organizations involved.

Because of implementation failure in the Co-WORK study, it remains unclear what the results of the new program would have been if the program had been executed as planned. Nevertheless, our comparison with other studies suggests that participatory RTW programs have a more beneficial effect for sick-listed workers with physical complaints and for those who have still an employment contract. Therefore, we can question ourselves whether the new program in its current form is actually suitable for our target population. More specifically, we can question ourselves whether this program sufficiently takes into account the challenges mentioned above. For example, the focus on direct placement in a competitive job, without ongoing benefits or intensive support, may have placed too high demands on all stakeholders involved, taking into account the perceived worse health of our target population, and the perceived inability of these workers to return to work early after sick-listing. Furthermore, in the new program the absence of a workplace to return to was considered an obstacle between the intention to return to work and actual RTW, while the absence of a workplace/employer also seems to affect the ASE determinants of RTW. The new program may not have sufficiently addressed all challenges that exist in the attitudes,

social influence and self-efficacy regarding RTW. This could suggest that also theory failure has played a role in the absence of a beneficial intervention effect.

Methodological considerations

There are some methodological features of this thesis that deserve consideration. Most of these methodological issues are related to the Co-WORK study, as this thesis mainly reports on this study.

A first relevant issue to consider is the outcome measure of the Co-WORK study, ie, duration until first sustainable RTW in a competitive job. An advantage of this outcome is that it can be considered robust, because it only includes sustainable RTW [10,11]. Furthermore, this outcome could be assessed with the use of registered data by the Dutch SSA, which is considered objective, accurate and complete. As a result, data on the primary outcome was complete for all participants. A disadvantage of this outcome measure is that the duration until first sustainable RTW is not only dependent on the OHC that has been delivered to the sick-listed worker by the SSA but is dependent on many factors [46], as was illustrated with the use of the ASE model. This means that, within the short time frame of one year, we could have expected only little effect of the intervention on our primary outcome measure. In our evaluation of the execution of the new program, some intermediate measures were assessed on which OHC may have a more direct influence, such as satisfaction with the program, the level of participation by the sick-listed worker in his/her own RTW process, and the degree of collaboration between the professionals of the SSA, the sick-listed workers' healthcare providers and the contracted vocational rehabilitation agencies. However, these intermediate measures were not assessed in the control group. As a result, we do not know whether the new program has had a beneficial effect on these intermediate outcomes.

Another relevant methodological issue to discuss is that we may have insufficiently addressed barriers for a successful execution of the new program before the RCT was started. Although interviews were held with several stakeholders, knowledge about these barriers was limited. Moreover, the target population was not consulted prior to the development of the new program. Instead, we used information about the needs of our target population resulting from previous studies [2,22,23].

A third relevant methodological issue is that sick-listed workers could only participate in the Co-WORK study if they had a positive intention to return to work, despite ongoing health complaints. Based on the results of the aforementioned study of Van Oostrom et al [11] such intention was considered an important precondition for the success of a participatory RTW program. However, in contrast to the findings for the subgroup with such positive intention in the study of Van Oostrom et al, no beneficial intervention effect was found in our study. Despite the selection based on this positive RTW intention, there were still challenges in influencing the ASE determinants of RTW. Some of these challenges may have played less of a role in the study of Van Oostrom et al, such as the absence of a workplace to return to. It is also possible that the use of a non-validated single-item questionnaire to assess this intention was inadequate. Possibly, it was difficult for sick-listed workers in our study to express their intention to return to work or to fully understand the concept. This means that we may not have been able to actually select participants with a positive RTW intention, despite ongoing health complaints.

A last relevant methodological issue is the design of the Co-WORK study, consisting of a RCT. This study design is considered the "gold standard" in evaluation research [46]. We believe that our study was in line with most of the CONSORT Statement requirements for high quality trials [47], although blinding participants and participating professionals for randomization was not possible due to the nature of the intervention. The pragmatic design of our RCT well reflects the potential effectiveness of such a new program in a real-life setting. However, because our study was conducted in daily practice, its conduct was also influenced by several organizational and environmental changes [48]. Further, some coordination, such as the provision of follow-up training sessions for the participating professionals in the program, was needed to facilitate the conduct of the RCT in practice. Although this coordination has resulted in a good internal validity, it implies some challenges regarding the external validity of our findings. Therefore, generalizing the results of our study to another setting should be done with great caution. Because from an international perspective social security systems differ greatly, generalizing our results to another country may be particularly difficult. Nevertheless, an important strength of our study in this regard is that in addition to evaluating the effectiveness of the new program, we also studied the execution of this program in practice and its additional costs, which makes our evaluation comprehensive and transparent.

Implications for research and practice

The findings of this thesis have several implications for research and practice. We can distinguish two major implications for research and four major implications for practice.

Implications for research

1. We recommend future studies evaluating a new RTW program to also include intermediate measures (output measures) on which the intervention will have a more direct influence, in addition to the desired outcome.
2. To prevent implementation and theory failure in future intervention research, we recommend to identify barriers for a successful implementation and to assess the specific needs and context of the target group in an early phase. Earlier studies on a participatory RTW program [22,23] showed that Intervention Mapping (IM) could be a useful tool to facilitate successful adoption and implementation of a new program by important stakeholder groups. The aim of this iterative process is to combine theoretical knowledge and empirical knowledge, including input and feedback from the main stakeholders [49]. IM could facilitate the identification of competing priorities at the organizational level and matching new tasks and responsibilities to existing ones. Furthermore, by involving the target population, IM may help to tailor the program to the specific needs and context of this group. In addition, we recommend future intervention studies aiming to enhance RTW of vulnerable workers, such as workers without an employment contract, older workers and workers with a low income, to pay specific attention to the larger social-political environment. The findings of this thesis illustrate that many challenges in improving RTW of these workers seem to result from social-political factors, such as the increase of flexible employment relationships, the limited availability of workplaces for vulnerable workers, and the poor collaboration between the different services involved. Future intervention studies focusing on a similar target population could also use the insights we obtained into specific challenges in improving RTW of workers without an employment contract, sick-listed due a CMD.

Implications for practice

1. We recommend professionals of the Dutch SSA to apply a participatory approach for the identification of RTW obstacles together with the sick-listed worker. Although the findings of this thesis provide no evidence for a beneficial effect of this approach on RTW of sick-listed workers with a CMD, our process evaluation revealed a high level of satisfaction with this approach among the stakeholders involved (chapter 4). Moreover, our qualitative evaluation showed that according to professionals of the Dutch SSA who applied this approach, it has led to a more active participation by the sick-listed workers in their own RTW process and has resulted in a better understanding of their barriers for RTW (chapter 5). However, better training of professionals in the application of a participatory approach is needed, because the resulting RTW action plans often did not explain adequately how a perceived obstacle for RTW could be overcome with practical solutions (chapter 4). Furthermore, we would like to emphasize that to enhance RTW of these workers, the development and evaluation of other or additional intervention components is necessary.
2. We recommend professionals and policy makers within the Dutch social security sector to create a RTW perspective for sick-listed workers without an employment contract. The results of this thesis demonstrate the importance of a workplace to return to, as this affects all ASE determinants of RTW and is very important in the step between the intention to return to work and actual RTW. The results of this thesis show that placement in a competitive job by a vocational rehabilitation agency can be very difficult to accomplish and seems to be dependent on several (social-political) factors (chapter 5). Therefore, it is important to consider alternative or additional measures. An alternative measure based on supported employment, an evidence-based approach for people with severe mental illness [37], may be the provision of ongoing support from a team of employment specialists and mental healthcare providers for both the sick-listed worker and his/her employer. A possible measure at policy level proposed earlier by Vermeulen et al [17], is realizing subsidized workplaces. Also a no-risk policy that compensates employers for future sickness absence costs, recently considered for (ex) cancer patients without an employment contract [50], may facilitate

sustainable RTW in a competitive job. Costs and benefits of these alternatives should be carefully considered.

3. We recommend professionals of the Dutch SSA to pay specific attention to the sick-listed worker's perceived ability to return to work early after sick-listing. The findings of this thesis illustrate that also this perceived inability influences all ASE determinants of RTW. A very recent study by Volker et al [51] showed a beneficial effect on the duration until first RTW of employees sick-listed due to a CMD of a blended web-based intervention including a module aimed at changing perceptions with regard to RTW while having symptoms, based on cognitive-behavioral principles. Possibly, also workers without an employment contract could benefit from a similar module. Therefore, we recommend professionals (and decision makers) of the Dutch SSA to carefully consider implementation of a similar module. In addition, also changing perceptions of OHC professionals regarding these sick-listed workers' ability to return to work early after sick-listing may be necessary.
4. Finally, all challenges in improving RTW of workers without an employment contract, sick-listed due to a CMD, reveal the importance of a better integration of services in (occupational) healthcare and vocational rehabilitation. Lessons may be learned from supported employment. In this approach integration of services is facilitated through regular meetings with all stakeholders involved, coordinated by a single case manager, which provide a vehicle for discussing clinical and rehabilitation issues relevant to work [37]. Such an approach may help to simultaneously address treatment and vocational needs, which may also increase the confidence in the sick-listed worker's ability to return to work. Further, this approach may facilitate continuity in care. However, to implement such a cooperation, it seems important that the professionals within these different disciplines acknowledge the mutual dependence of each other's service or knowledge, and it seems necessary to overcome practical barriers for collaboration [42]. Based on a Dutch study on collaboration between different healthcare professionals [42], we can recommend to emphasize the need for collaboration already in the education of these professionals.

Conclusions

The results of this thesis underline the need for further development of a suitable RTW intervention for workers without an employment contract, sick-listed due to a CMD. The new participatory supportive RTW program did not result in a (cost-effective) reduction in the duration until sustainable RTW of these vulnerable workers, compared to usual OHC. Therefore, we cannot recommend to implement the new program in the Dutch social security sector in its current form. The findings of this thesis provide important insights into the complex challenges in improving RTW of workers without an employment contract, sick-listed due to a CMD, and into the influence of these challenges on the attitude, social influence, self-efficacy and intention to return to work, and actual RTW of these workers. These insights can be used for the development and evaluation of a more suitable RTW program in future.

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Summary

General introduction

Background

Sick-listed workers without an employment contract have a more vulnerable position in the labor market compared to sick-listed employees. For these workers the absence of a workplace to return to can become a major obstacle for return to work (RTW). Further, compared to long-term sick-listed employees, long-term sick-listed workers without an employment contract often experience a worse health condition, have more psychosocial obstacles for RTW, are more often low skilled, and have less work experience.

In the Netherlands, the Dutch Social Security Agency (SSA) is responsible for occupational healthcare (OHC), including sickness benefit payment, for sick-listed workers without an employment contract. Workers belonging to this group are sick-listed unemployed workers, temporary agency workers and workers with an expired fixed-term contract. Many of these workers (about 40%) file a sickness benefit claim on the grounds of mental health problems. Nevertheless, evidence-based RTW interventions are still lacking for workers without an employment contract, sick-listed due to mental health problems.

World-wide, mental health problems, and in particular common mental disorders (CMDs) such as depressive, anxiety, and stress-related disorders, have become a growing cause of sickness absence, leading to high societal costs and individual suffering. Although in the international literature there is growing attention for the development and evaluation of interventions that aim to promote RTW of workers who are sick-listed due to a CMD, almost all these interventions assume the presence of a workplace to return to, and do not take into account changes in the labor market towards more flexible forms of employment.

This illustrates that both from a national and international perspective, there is a need for RTW interventions aimed at workers sick-listed due to a CMD, including those without an employment contract.

Aim of this thesis

The main aim of this thesis was to improve RTW of workers without an employment contract, sick-listed due to a CMD. The sub-objectives of this thesis were:

1. To get a broad understanding of factors that in the long run influence sustainable RTW of sick-listed workers with a CMD;

2. To develop a new participatory supportive RTW program for workers without an employment contract, sick-listed due to a CMD, based on a participatory RTW program, integrated care and direct placement in a competitive job;
3. To evaluate the execution of this new program in practice;
4. To evaluate the effectiveness and cost-effectiveness of the new program in shortening the duration until sustainable RTW in a competitive job.

Objective 1: to get a broad understanding of factors that in the long run influence sustainable return to work of sick-listed workers with a common mental disorder

Chapter 2 describes longitudinal associations between demographic, personality, disorder-related and work-related characteristics and sustainable RTW in two years of sick-listed workers with a depressive or anxiety disorder. We used data of a large Dutch cohort study, titled "The Netherlands Study of Depression and Anxiety" (NESDA). Logistic regression analyses were performed to study associations. Results of these analyses indicated that in the long-run younger age, higher household income and being (self-)employed are all together associated with higher odds of sustainable RTW in two years of sick-listed workers with a depressive or anxiety disorder.

Objective 2: to develop a new participatory supportive return to work program for workers without an employment contract, sick-listed due to a common mental disorder

Chapter 3 describes the development of the participatory supportive RTW program and the design of "The Co-WORK study" aiming to evaluate the (cost-)effectiveness of the new program, in comparison with usual OHC. The key component of the new program was a participatory approach, consisting of a stepwise process in which the sick-listed worker identifies obstacles for RTW and searches for solutions, together with a labor expert and RTW coordinator of the SSA. Direct placement in a competitive job and an integrated care approach were added to the protocol to facilitate RTW in the absence of a workplace to return to and to avoid conflicting advice by occupational and mental healthcare professionals. Vocational rehabilitation agencies were contracted to support the placement

in a suitable job. Further, cooperation between the insurance physician of the SSA and the sick-listed worker's healthcare provider(s) was stimulated.
The design of the Co-WORK study consisted of a randomized controlled trial (RCT) with two arms, an intervention and a control group, and a follow-up period of 12 months. Participants in both groups received usual OHC. In addition, participants in the intervention group were allocated to the new program.

Objective 3: to evaluate the execution of the new program in practice

Process evaluation
Chapter 4 contains a process evaluation of the new program. The main aim of this evaluation was to investigate which components of the program were realized in practice and to which extent these components were executed according to protocol. A total of 186 sick-listed workers participated in the Co-WORK study, of which 94 participants were randomly allocated to the new program. The process evaluation revealed that in practice only 36 of these participants actually had participated in this program. The most frequent reason for not participating in the program was a medical contra-indication, assessed by the insurance physician of the SSA. Fidelity to the protocol in these 36 cases was low to reasonable: in the RTW action plans, resulting from the participatory approach, it was often not explained properly how a perceived obstacle could complicate RTW; only two participants were placed in a suitable competitive job; execution of the program's consecutive steps was often not in accordance with the prescribed time frame; and in only half of the cases the insurance physician applied an integrated care approach. Still, most of the participants and professionals were satisfied with the participatory approach. The insurance physicians were also quite satisfied with the communication with the participants' healthcare providers. Participants and professionals were less satisfied with the execution of direct placement in a competitive job.

Evaluation of stakeholders' perceptions
Chapter 5 describes a qualitative evaluation of the new program. Interviews were held with two insurance physicians, three labor experts, three RTW coordinators, two case managers of vocational rehabilitation agencies and five sick-listed workers, who all had participated

in the new program. The objective of this study was to get a better understanding of the execution of the program in practice. Stakeholders' perceptions of the functions of the participatory supportive RTW program in practice and their perceptions of barriers and facilitators for a successful execution of the program within the Dutch social security sector were evaluated.

This evaluation revealed that according to professionals of the Dutch SSA, in practice the functions of a participatory approach and integrated care had been as intended, i.e., making a consensus-based RTW action plan, and improving communication and cooperation with the clients' healthcare provider(s). The sick-listed workers did not mention these functions. They stressed that they had received too little support by the SSA and the contracted vocational rehabilitation agencies. According to all stakeholders the job search based on the RTW action plans often had not resulted in direct placement in a competitive job. Reported barriers for a successful execution of the program were related to: 1. poor collaboration between the SSA, the vocational rehabilitation agencies and the (mental) healthcare sector; 2. the particular (health) problems experienced by the clients; 3. time constraints; and 4. limited opportunities in the Dutch labor market. Perceived facilitators for a successful execution of the program were: 1. reducing the number of SSA professionals involved; 2. earlier involvement of the vocational rehabilitation agency; and 3. making work arrangements with employers.

Objective 4: to evaluate the effectiveness and cost-effectiveness of the new program in shortening the duration until sustainable RTW in a competitive job

Effectiveness evaluation

Chapter 6 presents the results of the Co-WORK study. The main aim of this evaluation was to study the effectiveness of the new program in shortening the duration until first sustainable RTW in a competitive job, compared to usual OHC. Cox regression analysis was applied to study this outcome. This analysis revealed a hazard ratio (HR) of 1.15 (95% CI 0.61–2.16) (adjusted for possible confounders), which indicates no significant effect of allocation to the new program on the duration until first sustainable RTW. Also 'per-protocol analyses', including only those intervention group participants who actually had

participated in the new program (N=36), showed no significant effects of the program compared to usual OHC.

Cost-effectiveness evaluation

Chapter 7 presents from a societal perspective the cost-effectiveness of the new program in reducing the duration until first sustainable RTW in competitive employment and in gaining quality-adjusted life years, compared to usual OHC. In addition, return on investment (ROI) analyses were conducted from the social insurer's perspective.

The results of these analyses revealed that from a societal perspective, the new program was neither cost-effective in improving sustainable RTW nor in gaining QALYs. The maximum probability of cost-effectiveness was 0.64 at a willingness to pay of about €10 000 for one day earlier sustainable RTW. For QALYs gained the maximum probability of cost-effectiveness was 0.27, regardless of the willingness to pay. From the social insurer's perspective the estimated maximum probability of a positive financial return was 0.18.

General discussion

Interpretation of findings

The findings of this thesis reveal that some workers, such as workers without an employment contract, are more vulnerable than others when becoming sick-listed. The findings of this thesis also show that the new participatory supportive RTW program did not result in a (cost-)effective improvement in the duration until sustainable RTW of these workers, compared to usual OHC. Due to the low protocol adherence it remains unclear what the results would have been if the program had been executed as intended. A comparison of our findings with other studies on a participatory RTW program suggests a more beneficial effect of this type of program for sick-listed workers with physical complaints and for sick-listed workers who are still employed.

Our research reveals four main challenges in improving RTW of workers without an employment contract, sick-listed due to a CMD:

1. The absence of a workplace/employer;

2. Perceived ill-health and perceived inability to return to work early after sick-listing;
3. Poor collaboration between services in (occupational) healthcare and vocational rehabilitation;
4. Constraints in time or capacity within the organizations involved in OHC of these workers.

These four factors may have challenged the execution of the new program according to protocol, resulting in implementation failure. Further, it is also possible that the new program insufficiently addressed these challenges. This could mean that also theory failure has played a role in the absence of a beneficial intervention effect.

Implications for research and practice

The findings of this thesis have several implications for research and practice. We can distinguish two major implications for research and four major implications for practice.

Implications for research

1. We recommend future studies evaluating a new RTW program to also include intermediate measures (output measures) on which the intervention will have a more direct influence, in addition to the desired outcome;
2. We recommend to identify barriers for a successful implementation and to assess the specific needs and context of the target group in an early phase, to prevent implementation and theory failure in future intervention research.

Implications for practice

1. We recommend professionals of the Dutch SSA to apply a participatory approach for the identification of RTW obstacles together with the sick-listed worker. Nevertheless, to enhance RTW of these workers, the development and evaluation of other or additional intervention components is still necessary;
2. We recommend professionals and policy makers within the Dutch social security sector to create a RTW perspective for sick-listed workers without an employment contract;

3. We recommend professionals of the Dutch SSA to pay specific attention to the sick-listed worker's perceived ability to RTW early after sick-listing;
4. Finally, all challenges in improving RTW of workers without an employment contract, sick-listed due to a CMD, reveal the importance of better integration of services in (occupational) healthcare and vocational rehabilitation.

Conclusions

The results of this thesis underline the need for further development of a suitable RTW intervention for workers without an employment contract, sick-listed due to a CMD. The insights into the challenges in improving RTW of these workers, obtained through this thesis, can be used for the development and evaluation of a more suitable RTW program in future.

Samenvatting

Achtergrond

Mensen zonder (vast) dienstverband ervaren bij ziekte vaak meer barrières voor werkhervatting en een slechtere gezondheid dan zieke werknemers. Het ontbreken van een werkplek om naar terug te keren is een belangrijk obstakel bij re-integratie. In het kader van de Ziektewet is het in Nederland voor deze mensen mogelijk zich ziek te melden bij het Uitvoeringsinstituut Werknemersverzekeringen (UWV) en zodoende aanspraak te maken op een uitkering. UWV heeft als taak om hen "op te vangen" en terug naar werk te begeleiden. Mensen die aanspraak maken op een zogenaamde Ziektewetuitkering worden ook wel "vangnetters" genoemd. Tot de groep van "vangnetters" behoren zieke werklozen, uitzendkrachten en mensen met een einde dienstverband. Ruwweg 40% van de vangnetters heeft psychische klachten. Psychische klachten zijn daarmee de belangrijkste reden voor verzuim binnen deze groep.

Ook wereldwijd zijn psychische klachten een toenemende oorzaak van ziekteverzuim, met hoge maatschappelijke kosten als resultaat. Veelvoorkomende psychische klachten of stoornissen zijn depressiviteit, angstklachten en stress-gerelateerde klachten. In de internationale literatuur wordt in toenemende mate aandacht besteed aan het ontwikkelen en evalueren van interventies die werknemers met veelvoorkomende psychische stoornissen helpen het werk te hervatten. Echter, het merendeel van deze interventies veronderstelt de aanwezigheid van een werkplek om naar terug te keren en houdt geen rekening met veranderingen op de arbeidsmarkt naar meer flexibele vormen van arbeid.

Bovenstaande illustreert dat zowel vanuit een nationaal als internationaal perspectief er behoefte is aan een interventie die werkhervatting van mensen met veelvoorkomende psychische stoornissen bevordert, ook als zij géén arbeidscontract meer hebben.

Doel van het proefschrift

Het voornaamste doel van dit proefschrift was om na te gaan hoe werkhervatting van vangnetters met veelvoorkomende psychische stoornissen kan worden bevorderd. Concrete doelen waren:

1. Meer inzicht krijgen in factoren die invloed hebben op werkhervatting van mensen met veelvoorkomende psychische stoornissen;

2. Het ontwikkelen van een nieuwe participatieve ondersteunende methode (POM) voor terugkeer naar werk van vangnetters met veelvoorkomende psychische stoornissen, gebaseerd op een participatieve aanpak, geïntegreerde zorg en directe plaatsing in betaald werk;
3. Het evalueren van de uitvoering van POM in de praktijk;
4. Het evalueren van de effectiviteit en kosteneffectiviteit van POM in het verkorten van de duur tot aan duurzame werkhervatting in een betaalde baan.

Doelstelling 1: meer inzicht krijgen in factoren die invloed hebben op werkhervatting van mensen met veelvoorkomende psychische stoornissen

Hoofdstuk 2 beschrijft de mate waarin demografische kenmerken, persoonlijkheidskenmerken, psychische klachten en kenmerken van het werk van invloed zijn op werkhervatting in de twee jaar volgend op ziekmelding, bij zieke werknemers met een depressie of angststoornis. Voor deze studie werd gebruik gemaakt van data uit een grote Nederlandse cohortstudie, namelijk "De Nederlandse Studie naar Depressie en Angst" (NESDA).
Resultaten van deze studie laten zien dat op de lange termijn een jongere leeftijd, een hoger inkomen van het huishouden en het hebben van een arbeidscontract samenhangen met een grotere kans op werkhervatting van werknemers met een depressie of angststoornis.

Doelstelling 2: het ontwikkelen van een nieuwe participatieve ondersteunende methode voor terugkeer naar werk van vangnetters met veelvoorkomende psychische stoornissen

Hoofdstuk 3 beschrijft de ontwikkeling van POM en de opzet van de "SamenWERK" studie, gericht op het evalueren van de (kosten)effectiviteit van POM in vergelijking met de gebruikelijke begeleiding door UWV. Kern van POM is een participatieve aanpak, waarbij de vangnetter wordt gestimuleerd om zelf een plan van aanpak voor werkhervatting te maken, in samenwerking met zijn/haar re-integratiebegeleider en arbeidsdeskundige van UWV. Andere onderdelen van POM zijn geïntegreerde zorg, waarbij de verzekeringsarts van UWV afstemming zoekt met de behandelaar van de vangnetter om tegenstrijdige

adviezen te voorkomen, en directe plaatsing in passend betaald werk door een re-integratiebureau.
Deelnemers aan SamenWERK werden door middel van loting over twee groepen verdeeld: een controlegroep en een interventiegroep. Deelnemers in de controlegroep ontvingen alleen de gebruikelijke begeleiding van UWV, terwijl deelnemers in de interventiegroep naast deze gebruikelijke begeleiding ook werden toegewezen aan POM. Alle deelnemers werden 12 maanden gevolgd. De studie werd uitgevoerd in samenwerking met zeven UWV kantoren en drie re-integratiebureaus.

Doelstelling 3: het evalueren van de uitvoering van POM in de praktijk.

Procesevaluatie
Hoofdstuk 4 betreft een procesevaluatie van POM. Doel van deze evaluatie was om na te gaan welke onderdelen van POM in de praktijk waren gerealiseerd (volgens protocol). In totaal namen 186 vangnetters deel aan SamenWERK, van wie 94 deelnemers op basis van loting werden toegewezen aan POM. De procesevaluatie laat zien dat in de praktijk slechts 36 van deze deelnemers daadwerkelijk aan dit nieuwe programma deelnamen. De belangrijkste reden om niet aan POM deel te nemen was een medische contra-indicatie, vastgesteld door de verzekeringsarts van UWV. In de 36 gevallen waarin wel aan POM werd deelgenomen was de protocoltrouw slecht tot matig: barrières voor werkhervatting werden vaak niet duidelijk omschreven in de plannen van aanpak; slechts twee deelnemers werden door één van de gecontracteerde re-integratiebureaus geplaatst in een passende betaalde werkplek; de begeleiding was vaak vertraagd; en de verzekeringsartsen van UWV namen slechts in de helft van de gevallen contact op met de behandelaar van de deelnemer. Desondanks waren veel deelnemers en professionals van UWV tevreden met de participatieve aanpak en het hieruit voortkomende plan van aanpak. De verzekeringsartsen waren ook redelijk tevreden met de communicatie tussen hen en de behandelaren van de deelnemers. De tevredenheid met de begeleiding naar een passende betaalde functie door de re-integratiebureaus was het minst groot.

Evaluatie van de perceptie van stakeholders

Hoofdstuk 5 beschrijft een kwalitatieve evaluatie van POM, aan de hand van percepties van de belangrijkste stakeholders. Interviews werden gehouden met twee verzekeringsartsen, drie arbeidsdeskundigen, drie re-integratiebegeleiders, twee casemanagers van re-integratiebureaus en vijf deelnemers, die allen betrokken waren geweest bij de uitvoering van POM of aan het programma hadden deelgenomen. Doel van deze evaluatie was om na te gaan of de verschillende onderdelen van POM – een participatieve aanpak, geïntegreerde zorg en directe plaatsing in betaald werk – in de praktijk de beoogde functies hadden en of er in de praktijk barrières bestonden voor een succesvolle uitvoering van POM.

De uitkomsten van deze evaluatie wijzen uit dat volgens de professionals van UWV de participatieve aanpak en geïntegreerde zorg in de praktijk de beoogde functies hadden. De deelnemers herkenden dit niet. Zij gaven aan te weinig begeleiding te hebben ontvangen van UWV en/of de re-integratiebureaus. Volgens alle stakeholders had de begeleiding naar een passende werkplek door de re-integratiebureaus vaak niet geleid tot directe plaatsing in passend betaald werk en was zodoende de uitvoering van POM niet verlopen als bedoeld. Verschillende barrières werden genoemd voor een succesvolle implementatie van POM, zoals: 1. de beperkte samenwerking tussen UWV, re-integratiebureaus en de zorgsector; 2. de ernst van de psychische klachten; 3. conflicterende prioriteiten bij UWV en de re-integratiebureaus; en 4. het beperkte aantal beschikbare banen vanwege de economische recessie. Verwacht werd dat implementatie kon worden bevorderd door: 1. het verminderen van het aantal betrokken professionals; 2. een eerdere betrokkenheid van de re-integratiebureaus; en 3. door het maken van afspraken met werkgevers over het met voorrang aanbieden van mogelijke vacatures.

Doelstelling 4: het evalueren van de effectiviteit en kosteneffectiviteit van POM in het verkorten van de duur tot aan duurzame werkhervatting in een betaalde baan

Effectevaluatie

Hoofdstuk 6 beschrijft de effectiviteit van POM in het verkorten van de duur tot aan duurzame betaalde werkhervatting, in vergelijking met de gebruikelijke begeleiding door UWV. Met duurzame werkhervatting wordt bedoeld: werkhervatting gedurende tenminste 28 opeenvolgende dagen. De effectevaluatie laat zien dat toewijzing aan POM geen effect

had op de duur tot aan duurzame betaalde werkhervatting. Het aantal deelnemers dat het werk duurzaam hervatte en de duur tot werkhervatting verschilden niet significant tussen de interventie- en controlegroep. Na 327 dagen in de interventiegroep en 302 dagen in de controlegroep had in beide groepen tenminste een kwart van de deelnemers het werk hervat. Ook waren er geen significante verschillen in werkhervatting tussen de controlegroep en alleen die 36 deelnemers uit de interventiegroep die daadwerkelijk aan POM hadden deelgenomen.

Kosteneffectiviteitsevaluatie

Hoofdstuk 7 beschrijft de kosteneffectiviteit van POM in het verkorten van de duur tot aan duurzame betaalde werkhervatting en in het bevorderen van voor kwaliteit van leven gecorrigeerde levensjaren ("quality-adjusted life years" = QALYs), in vergelijking met de gebruikelijke begeleiding door UWV, vanuit het maatschappelijke perspectief. Tevens werd een kostenbatenanalyse uitgevoerd vanuit het perspectief van UWV.

De resultaten van deze analyses laten hogere interventiekosten en medische kosten zien voor de interventiegroep. De maximale kans dat POM kosteneffectief werd bevonden was 0,64 bij besteding van €10 000 per dag eerdere werkhervatting. De maximale kans dat POM zou leiden tot een kosteneffectieve toename van QALYs was 0,27 onafhankelijk van het bedrag dat iemand hiervoor zou willen betalen. Vanuit het perspectief van UWV was de kans op financiële opbrengsten van POM 0,18. Deze resultaten laten zien dat vanuit maatschappelijk perspectief de kans klein is dat POM kosteneffectief wordt bevonden. Tevens laten de resultaten een kleine kans zien op positieve opbrengsten van het programma voor UWV.

Algemene discussie

Interpretatie van bevindingen

De bevindingen van dit proefschrift laten zien dat mensen zonder (vast) dienstverband kwetsbaarder zijn dan werknemers met een dienstverband op het moment dat zij ziek worden. De resultaten van dit proefschrift laten tevens zien dat POM in vergelijking met de reguliere begeleiding voor vangnetters niet resulteerde in een snellere, duurzame werkhervatting in betaald werk. Vanwege een geringe protocoltrouw weten we niet wat de

resultaten zouden zijn geweest wanneer POM was uitgevoerd zoals bedoeld. Een vergelijking van onze bevindingen met die in andere studies suggereert meer positieve resultaten van een participatieve aanpak voor werknemers met fysieke klachten en voor degenen die nog beschikken over een dienstverband.

Dit proefschrift laat vier belangrijke uitdagingen zien bij het bevorderen van werkhervatting van vangnetters met veelvoorkomende psychische stoornissen:

1. De afwezigheid van een werkplek/werkgever.
2. De veronderstelde slechtere gezondheid van vangnetters en de verwachting bij zowel vangnetters als betrokken professionals dat een snelle terugkeer naar werk niet mogelijk is.
3. De beperkte samenwerking tussen diensten in de sociaal-medische en curatieve zorgsector en de re-integratiedienstverlening.
4. Beperking in tijd en capaciteit bij organisaties die betrokken zijn in de begeleiding van vangnetters.

Deze vier factoren vormden een uitdaging bij de uitvoering van POM in de praktijk, waardoor POM vaak niet werd uitgevoerd zoals beoogd ("implementation failure"). Mogelijk werden in POM bepaalde uitdagingen ook onvoldoende aangepakt ("theory failure").

Implicaties voor onderzoek en praktijk

De bevindingen van deze thesis hebben verschillende implicaties voor onderzoek en praktijk.

Implicaties voor onderzoek

1. We raden onderzoekers aan om bij de evaluatie van een interventie voor werkhervatting ook intermediaire uitkomstmaten mee te nemen waarop de interventie een meer directe invloed heeft;
2. Om "implementation failure" en "theory failure" in toekomstig interventieonderzoek tegen te gaan, adviseren we barrières voor succesvolle implementatie en specifieke behoeften van de doelgroep in een vroege fase te identificeren.

Implicaties voor de praktijk

1. We adviseren professionals van UWV om een participatieve aanpak toe te passen bij het identificeren van knelpunten voor werkhervatting samen met de vangnetter. Desondanks willen we benadrukken dat om werkhervatting te bevorderen de ontwikkeling en evaluatie van andere of additionele interventiecomponenten noodzakelijk is;
2. We adviseren professionals en beleidsmakers werkzaam in het domein van sociale zaken en werkgelegenheid meer arbeidsmogelijkheden te creëren voor vangnetters;
3. We adviseren professionals van UWV om specifieke aandacht te besteden aan de overtuiging van sommige vangnetters en professionals dat een snelle werkhervatting van vangnetters met psychische klachten niet mogelijk is;
4. Tenslotte laten alle uitdagingen in het bevorderen van werkhervatting van vangnetters met veelvoorkomende psychische stoornissen het belang zien van een betere integratie en samenwerking van diensten binnen de sociaal medische en curatieve zorgsector en de re-integratiedienstverlening.

Conclusies

De resultaten van dit proefschrift benadrukken de noodzaak voor de verdere ontwikkeling van passende interventies voor werkhervatting van vangnetters met veel voorkomende psychische stoornissen. Inzichten in belangrijke uitdagingen in het bevorderen van werkhervatting van deze groep, verkregen door dit proefschrift, kunnen worden gebruikt ten behoeve van de toekomstige ontwikkeling van een beter passend begeleidingsprogramma.

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Leescommissie

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‘There never seems to be enough time

To do the things you want to do

Once you’ve found them

But I’ve looked around enough to know

That you’re the one I want to go

Through time with.’

♥.

List of publications

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Lammerts L, Vermeulen SJ, Schaafsma FG, Van Mechelen W, Anema JR. Return to work of workers without a permanent employment contract, sick-listed due to a common mental disorder: design of a randomised controlled trial. BMC Public Health. 2014;14:594.

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About the author

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Lieke Lammerts was born on March 21st 1987 in Elst (Gelderland), the Netherlands. After completing secondary school (VWO) at the Overbetuwe College in Bemmel, she started her studies in Health Sciences at the University of Maastricht in 2005. In 2008 she graduated cum laude from the Bachelor's program. In the same year she attended the pre-master's program in Governance and Organization Science at the University of Utrecht. After completing a minor in Law at the University of Amsterdam, she finished this pre-master in 2009. In 2010, she obtained a Master's degree in Governance and Organization Science. Still interested in public health, Lieke completed another Master's program in International Public Health at the VU University of Amsterdam in 2011. During this program she worked as an intern for three months at the World Health Organization in Geneva. In November 2011, Lieke started with her PhD at the EMGO+ Institute, within the department of Public and Occupational Health of the VU Medical Center. The results of this study on return to work of workers without an employment contract, sick-listed due to a common mental disorder, are presented in this thesis. During her PhD, she obtained a master's degree in Epidemiology and a University Teaching Qualification. Lieke is currently working as a research consultant at Zilveren Kruis.


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