

Vitalis

A randomized intervention and
coordination program aiming at
Return To Work for women with
long term sick leave

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Sammanfattning

Vitalis var en randomiserad kontrollerad interventionsstudie som vände sig till långtidssjukskrivna kvinnor i Uppsala län. Deltagarna var sjukskrivna på grund av psykisk ohälsa och/eller smärta och väntades inom kort uppnå maxgränsen i sjukförsäkringen (utförsäkras). Av totalt 947 som utförsäkrades under perioden 2010-2012 uppfyllde 648 stycken projektets inklusion- och exklusionskriterier och tillfrågades om deltagande. Av dessa tackade 327 stycken (50,4 %) ja till studien varpå de randomiserades till att hamna i någon av följande grupper: 1) multimodal teambehandling (TEAM) 2) psykoterapi med Acceptance and Commitment Therapy (ACT) eller 3) kontrollgrupp. Det huvudsakliga syftet med studien var att underlätta arbetsåtergång (förhindra återgång i sjukförsäkringen) samt att förbättra deltagarnas hälsa under projekttiden på ett år.

Deltagarna i TEAM-gruppen erhöll individuellt möte med läkare, psykolog, arbetsterapeut och socionom som var och en bedömde deltagarens problematik i relation till arbetsåtergång. TEAMET tog sedan fram en gemensam individualiserad plan med förslag på åtgärder och behandling, där deltagarna erbjöds och sedermera tackade ja till psykoterapi (60 %, genomsnitt 9,2 träffar); arbetsterapeut (72 %, genomsnitt 3,7 träffar); socionom (36 %, genomsnitt 6,5 träffar) samt ytterligare medicinska åtgärder initierade av läkare (41 %). I ACT-gruppen erhöll alla deltagarna psykoterapi med ACT med i genomsnitt 10,0 träffar under projektåret.

Utöver behandling erhöll deltagarna i interventionsgrupperna "samverkan" mellan Försäkringskassan och Arbetsförmedlingen i syfte att förankra deltagarnas rehabiliteringsmål. Samverkan innebar att någon av behandlarna deltog i överlämnings- och planeringsmöten under utförsäkringen och introduktionsprogrammet inom Arbetsförmedlingen.

Deltagarna svarade under projektåret vid tre tillfällen på enkäter där de skattade sin syn på arbetsförmåga/möjligheter och olika aspekter på sin hälsa. Ett år efter utförsäkringen samlades data in från Försäkringskassan huruvida deltagarna återvänt till sjukförsäkringen samt antalet ersättningsdagar från Försäkringskassan under det gångna året.

Medelåldern på deltagarna var 48,5 år och deras genomsnittliga sjukskrivningstid var 7,5 år (spridning 1-16 år). Knappt 2/3 hade en anställning.

Ett år efter utförsäkringen hade 56,9 % i ACT-gruppen, 60,8% i TEAM-gruppen och 48,5% i kontrollgruppen INTE återvänt till sjukförsäkringen.

Den positiva tendensen till mindre återgång i sjukförsäkringen uppnådde inte statistisk signifikans. Det var heller inte någon statistiskt signifikant skillnad i antalet ersättningsdagar från Försäkringskassan under år 1 mellan grupperna, även om det fanns en positiv trend för TEAM-gruppen.

Hälsan, mätt med GHQ (General Health Questionnaire), förbättrades signifikant i TEAM-gruppen. Båda interventionsgrupperna uppvisade även en förbättrad psykisk hälsa med mindre ångest och depression mätt med HADS (Hospital Anxiety and Depression Scale). Deltagare i ACT-gruppen förbättrade signifikant sin upplevelse av smärta under uppföljningsåret.

Self-efficacy var lågt och då speciellt för gruppen som inte var födda utanför Sverige.

Intervjuer som genomförts med personal som arbetat med arbetslivsinriktad rehabilitering i projektet har analyserats utifrån innehållsanalys.

Preliminära resultat visar att samverkan för arbetsåtergång, individuella faktorer och tillgång till arbetsplatser är faktorer som främjar återgång i arbete. Hindrande faktorer kan bestå utav avsaknad av kommunikation och parallella processer samt svårigheter med fördelning av ansvar, otydlighet och revirbevakning.

Summary

Vitalis was a randomized controlled intervention study that addressed women on long-term sick leave in Uppsala County. Participants were on sick leave due to mental illness and/or pain and were expected to reach the time limit within the in health insurance. Of the total of 947 eligible reaching the time limit during 2010-2012, 648 persons met the projects inclusion- and exclusion criteria and were invited to participate. Of these, 327 persons (50.4%) gave informed consent and was thereafter randomly assigned one of the following groups: 1) multimodal team treatment (TEAM) 2) psychotherapy with Acceptance and Commitment Therapy (ACT), or 3) control group. The main purpose of the study was to facilitate the return to work (preventing a return to the public health insurance) and to improve participants' health during the project period of one year.

The participants of the TEAM group received individual meetings/assessments with a doctor, psychologist, occupational therapist and social worker, each assessing the participant's problems in relation to the return to work goal. The TEAM worked out an individualized plan of actions/treatments, which then was presented to the participant. Suggested and accepted actions were psychotherapy (60%, average 9.2 sessions); Occupational Therapist (72%, average 3.7 sessions); social worker (36%, average 6.5 sessions) and further medical investigations/referrals initiated by physicians (41%).

In the ACT group all participants received psychotherapy with ACT with an average of 10.0 sessions (range 1-23) during the project year.

In addition to the medical assessment/treatments all participants in the intervention groups also participated in scheduled collaboration meetings with representatives from the health insurance agency and employment office in order to establish an agreement and justification on the rehabilitation goals. The participant and a health professional from the project participated in these collaborations meetings.

During the project year the participants filled in questionnaire at three points in time in which they rated their views on returning to work as well as various aspects of their health. Data whether the participants had returned to the health insurance as well as the number of reimbursed days during the first years, was collected from the health insurance register after one year.

The average age of participants was 48.5 years and the average time on sick leave was 7.5 years (range 1-16 years). Just under two thirds had still an employer.

At one year follow-up: 56.9% in the ACT group, 60.8% of the TEAM group and 48.5% in the control group had NOT returned to the health insurance

system. The positive trend did, however, not reach statistical significance. There was no significant difference in the number of reimbursed days between the intervention groups and control group, although there was a positive trend for the TEAM group.

Health, as measured by the GHQ (General Health Questionnaire), was significantly improved in TEAM Group. Both intervention groups also showed improved mental health with less anxiety and depression measured by the HADS (Hospital Anxiety and Depression Scale). Participants in the ACT group significantly improved their pain during the follow-up year.

Results also showed that mean General self-efficacy values were low, especially for women born abroad.

Preliminary results on the qualitative assessment of data collected from the rehabilitation organizations showed that close cooperation between professionals, individual factors such as motivation, the possibility to offer individual support and access to working places are factors that support individuals on long term sick absence to return to work. Prohibitive factors are lack of communication and parallel processes and difficulties in distribution of responsibility, lack of clarity and not sharing expertise with each other.

Background and Introduction

Like many western countries Sweden has been challenged by a high number of number of people being outside the labour market due to health reasons. The rise in long-term sick leave during the past two decades has mainly been caused by a rise in mental health problems, which today, along with chronic pain, are the most common reasons for long-term sickness absence.¹⁻³

Work and being able to work is important to most people. It does not only provide reimbursement for living, but it also offers meaningfulness, friends and societal and social participation. Thus, being unwantedly outside the labour market due to health reasons may further affect ones health and functioning negatively. There is evidence that persons on long-term sick leave due to psychiatric disorders are at risk of future deteriorating health and premature mortality.^{4,5} Thus, helping persons on long term sick leave back to a meaningful work may be an effective method to achieve and maintain a better health.

The increase of mental ill health is also of societal interest as it has been discussed as an economic threat to the welfare state.⁶ The economic burden of psychiatric disorders has increased dramatically in Sweden where the main costs are indirect, which includes costs of the number of insurance reimbursed sick-days.⁷ Consequently, society has several reasons to aid individuals on long-term sick leave due to mental ill health and chronic pain to return to work.

There is a gender difference in long-term sick leave (in Sweden as well as well as in many comparable and neighbouring countries). Since several decades back there have been a higher proportion of women than men on long-term sick leave. The gender gap is clearly evident in sickness absence due to mental ill health.⁸ The reasons for the gender gap in sickness absence are unknown, but several hypotheses have been proposed; these include gender differences in health care utilization, rehabilitation activities, work conditions and type of employer and household situation.⁹ Further, the risk receiving sick leave benefits is associated with sociodemographic and socioeconomic factors, where persons having more education and higher salaries are at lower risk. Overall, the higher prevalence of mental ill health in women combined with more family responsibility, lesser paid jobs and less active rehabilitation activities put women in vulnerable situation.^{8,9}

The proportion of the working force being outside the labour market due to ill health differs between countries, suggesting that contextual and structural factors may play an important role. The sharp raise in persons on long-term sick leave in Sweden in the beginning of the millennium initiated several regulatory and political actions in Sweden.¹⁰ One major change was carried

out in 2008, when the Swedish parliament adopted a new political act reforming the sick leave system. Prior this regulatory change, persons with persistent long-term illness affecting their work ability, would routinely have their provisional sick absence prolonged for yet another year, which enabled potentially very long periods leave with health insurance cover. The new act, adopted in 2008, introduced a time limit of one year for non-critically ill patients on sick leave. Patients reaching the maximum period are since then routinely transferred to the Swedish Public Employment insurance, for a three-month re-examination programme, aiming at return to work in a controlled or competitive employment.

During 2010-2012, which was the setting for the current project, 41,000 persons in Sweden lost their sick leave benefits (In Swedish: "utförsäkrades") as they reached the newly introduced time restriction. This put forth a form of a natural experiment, where persons lost their health insurance benefits and were expected to try to return to work, despite likely still having various health problems. The current project aims at trying to facilitate the return to work process for this group.

There are many different types of interventions aiming at facilitating and hasten return to work (RTW) for persons on long-term sick leave due to mental illness. There are mono therapy approaches, which often include psychotherapy such as cognitive behavior therapy. There are also multidisciplinary or multimodal rehabilitation approaches¹¹ trying to address several different hindrances of RTW within the bio-psycho-social model of health. Such multimodal approaches often include different specialists, such as physicians, psychologists, physiotherapists and work/rehabilitation therapists.

Further, vocational interventions aiming at RTW may be set up in partnership with other organizations, which is the case in supportive employment (SE) and individual placement and support (IPS) where health care treatment professionals work in close integration with different employment services.¹² One further aspect on vocational interventions is whether it addresses specific health problems or diagnoses, which limits the results generalizability to specific groups, or if it should address a more general population, thus investigating evidence more of general effectiveness.

A recent Cochrane systematic review, based on 14 randomized trials, concluded that supportive employment seems to be effective in improving a number of vocational outcomes relevant to people with severe mental illness.¹²

There is also evidence that a multidisciplinary and interventional approach seems to be effective for physical complaints as well as psychological complaints.^{11,13,14}

In this randomized controlled study we aimed at investigating one unimodal (ACT) and one multimodal (TEAM) approach to facilitate return to work in individuals reaching the maximum time restriction within the health insurance system.

Purpose and Hypothesis

The overall purpose of the present study was to gain knowledge in methods effective in facilitating return to work in persons with long-term sick leave methods due to mental ill health and/or chronic pain.

The specific primary goals were:

- To investigate if unimodal rehabilitation with acceptance and commitment therapy (ACT¹⁵, i.e. a form of cognitive behavioural therapy) increases 1) health and 2) return to work compared to control at one year.
- To investigate if multimodal rehabilitation with individualized assessment and treatment plan increases 1) health and 2) return to work compared to control at one year.
- To investigate and describe health in the study population using validated assessment instruments

Secondary goals included:

- To investigate, using qualitative methods, the views on cooperation ("samverkan") among the rehabilitation organisations involved in the project
- To investigate and describe self-efficacy in the study population and the relation between self-efficacy and view of the future, social relations, health and background variables.
- To investigate predictors associated with positive return to work outcome at one year.
- Investigate the study populations experience of the time in the Working life Introduction programme ("introduktionsprogrammet"), organized within Labour Market Policy programme

Methods

Vitalis was an intervention study designed as a randomized controlled trial. The main objective was to investigate whether persons in either of the two study arms receiving intervention would be more likely to return to work (RTW), where RTW was assessed as having returned to health insurance benefits one year after losing it. A secondary RTW-outcome was to investigate if there were a difference between the interventions and control group in number of fully reimbursed insurance days during the first year.

Vitalis had several additional objectives, which are described above. These included descriptive quantitative analyses and also qualitative analyses. The additional research questions were secondary to the study design.

The target group included every person in Uppsala County on long-term sick leave due to mental ill health and/or chronic pain, and who were expected to reach their maximum of health insurance benefit during 2010-2011. A total of 947 persons, on sick leave due to the defined health problems and expected to reach the time maximum, were identified at the local health insurance office (Försäkringskassan Uppsala). A physician together with a psychologist or work therapist then scrutinized the sick leave certificates by the inclusion and exclusion criteria.

The inclusion criteria were: 1) female gender 2) on sick leave for mental ill health/ chronic pain, 3) age 20-64 years.

The exclusion criteria were: 1) Known suicidal risk 2) Current abuse of alcohol or drugs 3) Severe mental illness, such as psychosis, bipolar depression type 1, mental retardation or severe personality disorder. 4) No or very limited Swedish language skills.

Initially current on-going psychotherapy or current on-going other rehabilitation activities were used as an additional exclusion criterion to avoid therapeutic interference. However, as the information at the health insurance office rarely was accurate or updated about the current situation, this criterion was not considered adequate and was thus skipped.

When the sick-leave certificates were scrutinized 299 of the 947 were excluded, where the main reasons for exclusions were having clearly wrong diagnosis or too severe mental illness. Other reasons for exclusion were changes in the individual's health insurance status (for example: leaving it or receiving permanent pension) or moving from the County, suicidal risk, no Swedish language skills or present substance abuse.

The 648 persons fulfilling the inclusion and not the exclusion criteria were then contacted by mail and were given information about the study and were invited to participate. Of these, 327 (50 %) gave informed consent and were then block randomized to one of the three conditions being 1) Unimodal

ACT 2) Multimodal team assessment and individualized treatment plan (including possibility of individual ACT) or 3) control, which was "treatment as usual" within the routine work of the health insurance office in cooperation with the employment insurance office. The control group did not meet with any health professional within the project, but were free to access other health care professionals, as they needed.

The 13 first participants started treatment before formal ethical approval of the research study and where thus excluded from research. An additional six individuals were excluded during the project because of severe somatic/mental disease or withdrawn consent, which resulted in an ACT-study group of 102 individuals, TEAM-group of 102 and a control group of 104.

In both treatment groups (ACT 16, TEAM 18) several individuals chose not to show at all, thus not receiving any type of assessment/interventions, thus making it possible to evaluate an intention-to-treat population or just the once receiving intervention.

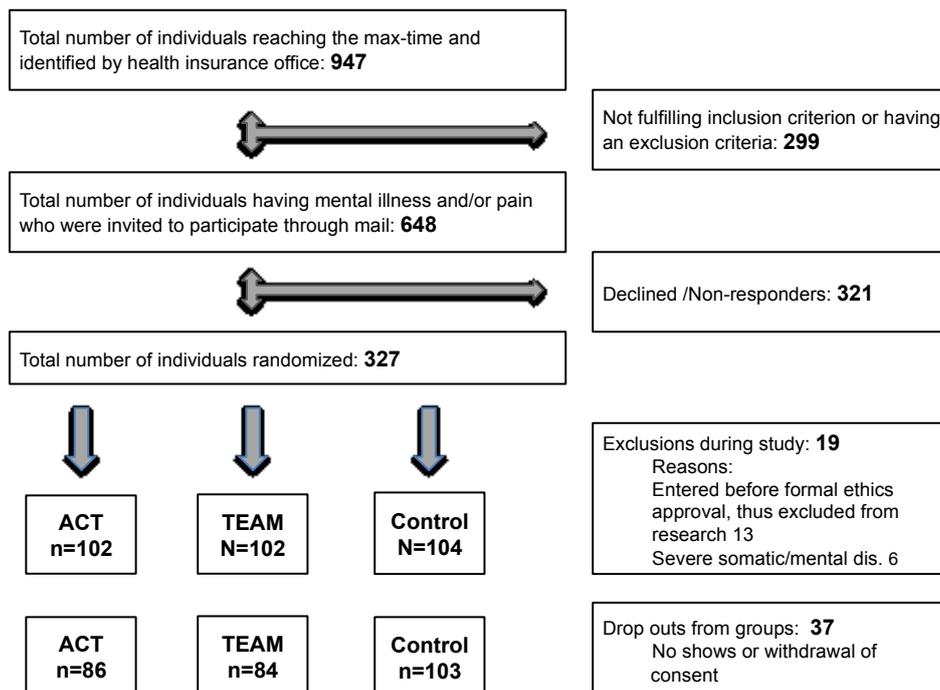


Figure 1. Flow chart figure of recruitment, randomization and drop out.

The inclusion, randomization and group allocation was performed consecutively during the project, about 3-4 months ahead the date when the participants were expected to lose their sick leave benefits.

Participants in both interventions groups also received, apart from the therapeutic activities, support and collaboration with the social insurance system, the employment office and, if applicable, employer during the project time of one year. The main aims of this cooperation (“samverkan”) was to reach consensus about each individual’s return-to-work goal and time frame for this, as the individual would move between the insurance systems over the project year and along with this receive therapeutic intervention. One specific aim with the Vitalis project was to assess and evaluate the process and quality of this cooperation.

The two different interventions are described below, for a more detailed description; please see the "Behandlingsmanual" (in Swedish).

Apart from the interventions, the participants (also the control group) were followed with questionnaires at three different points in time: prior the interventions (base line), at seven and at twelve months. These questionnaires contained questions about the participant's social situation, country of birth, education, and number of children in household, lifestyle and household economy. The health situation was repeatedly assessed with SWLS (Satisfaction With Life Scale)¹⁶, HADS (The Hospital Anxiety and Depression Scale)¹⁷, the GHQ-12 (General Health Questionnaire)¹⁸, the General Self-efficacy Scale¹⁹ and Self-Rated Health/Sleep was assessed with the question: “In general, how would you rate your health/sleep?” Both questions used the response categories very good, good, neither good nor poor, poor and very poor.

The participants in the interventions groups were further clinically screened for psychiatric disease using the MINI international neuropsychiatric interview²⁰ and assessed using the patient’s GAF scale (global assessment of functioning).²¹ Participants who received interventions also performed a self-rating MADRS (Montgomery–Åsberg Depression Rating Scale).²²

Multimodal assessment and individualized treatment (TEAM)

The multidisciplinary team consisted of a physician, a psychologist, an occupational therapist and a social worker. The team specialists met with the participant separately for 1.5-2 hours to assess the situation from their specific perspective. The aim was to perform all four assessments within a week, although this was not always possible mainly due to reschedules by the participants. When each specialist had met the participant the team members met without the participant to consider the situation as well as the participant’s strengths and hindrances for returning to work. The team compiled an individualized plan, with the main purpose of facilitating the participant’s chances of returning to work. The team strived for consensus when formulating the plan. One of the team specialists were assigned as the participants contact person and met with the participant to present the suggested rehabilitation plan. The participants had the choice of accepting the whole, none or parts of the plan and the goal was to achieve mutual commitment.

Typical interventions suggested by the team specialists were for physician: further medical investigations, referral to or contact with other or regular

caregiver(s); for psychologist: psychotherapy with ACT (see description below); for occupational therapist: activity analysis, home and/or work visit, activity training alone or in group; for social worker: help with evaluation of social and/or financial situation including advice of potential support or right of publicly financed benefits.

Typically a participant would meet with one, two or three specialist over several months, whereas some were followed with personal meetings over the project year. Psychotherapy with ACT was suggested and accepted for 60% of participant, where the participant on average met with the therapist for 9.2 sessions (range 0-31). Evaluation and training with a work therapist (individual or in group) was suggested and accepted in 72% of participants (average number of meetings 3.7; range 1-20). Counseling by a social worker was suggested and accepted in 36% of the participants (average number of meetings 6.5; range 1-20). More medical attention by the physician other than the initial meeting was performed in 41% of the participants.

The team met weekly to evaluate the situation and to synchronize the planned or ongoing activities and treatment for the participants currently under treatment in the project.

If considered necessary it was possible for the specialists to perform their assessments and therapeutic treatment outside the clinic, mainly in the participant's home environment or performing a work visit (mainly with the work therapist).

Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT) is a form of Cognitive Behavioral Therapy (CBT) that uses acceptance and mindfulness strategies, together with behavioral strategies to increase function and quality of life rather than decreasing symptoms.²³

ACT therapy was planned individually for all in the ACT-group and 60% of the participants in the multidisciplinary group. Most sessions occurred at the clinic but it was also possible for the therapist to perform sessions at the patients home, work or other where. Sessions were normally about an hour long. All participants had the chance of keeping contact with their therapist through re-visits or telephone follow-ups during their time in the project. An Internet module was developed containing films and instructions supportive of the physical meetings.

The average number of ACT-session in the ACT-group was 10.0 (range 1-38).

Cooperation (samverkan)

All participants in the intervention groups (ACT and TEAM) also received a structured collaboration with the local health insurance office and the local unemployment office. During the project year the participant's would move from one insurance system to the other, hopefully well enough to remain within the unemployment insurance as a job applicant or even getting a job. Over the intro the participant and their contact person within the project met with representatives from the health and unemployment offices. The main objective was to increase the participant's commitment as an active part in his or her own rehabilitation process as well as setting adequate expectations and goals. The cooperation as well as the participants' experiences within the intro was both targets for evaluation.

Gender perspective

Vitalis was, by design, a project open only for women, as women are overrepresented in long-term sick leave and since some of the hindrances in RTW are believed to be gender specific.

Statistics and Analysis

Two main outcomes were used in the evaluation of the interventions effect on RTW, both using register data from health insurance system. The first was a dichotomous variable whether participants received any benefits (reimbursements) from the health insurance system one year after being forced to leave this system. Thus, this variable measured the proportion of persons returning to the health insurance. Chi-square tests were used to assess group differences in proportions.

The second outcome variable was a continuous variable of full-reimbursed insurance days (either sick leave days or sick pension days computed as full days) from the health insurance system during the year after being forced to leave the system. Since all participants were transferred to the employment insurance system for a minimum of three months during this time, this outcome variable typically ranged from 0 to 275 full days. The variable was non-normally distributed and non-parametric statistics were used to assess differences between intervention and control group.

Sick leave periods shorter than 14 days are refunded directly by the employer and not by the health insurance, thus short time sick absence during follow-up, if such occurred, is not included in the outcome measure.

Differences in health outcomes between intervention and control groups were analyzed with T-test and ANOVA (also for repeated measures).

Among the secondary research questions investigating differences on subgroup levels, T-tests and ANOVA has been applied to continuous variables (also for repeated measures), chi-square on proportions and logistic regression to assess predictors. A post hoc test was used to test how groups differed to each other. Pearson's correlation test was used to investigate the relationship between variables.

To explore the set of variables predicted self-efficacy multiple regression analysis was performed.

To investigate the views on cooperation among the rehabilitation organization's involved in the project content analyses were used.²⁴

All data analyses were carried out using the Statistical Package for the Social Sciences version 21 (IBM Corp., Armonk, New York, USA).

Results

The results are presented as follows:

- 1. Baseline characteristics of study group**
- 2. Intervention effects on mental health**
- 3. Self-efficacy in the population**
- 4. Intervention effects on return to work**
- 5. Predictors of success (RTW)**
- 6. Assessment of participants' views on the time in "Intro"**
- 7. Qualitative evaluation on project cooperation**

1. Base line characteristics of study group

Participants were, on average, 48.5 years old and had been on insurance benefit leave for on average 7.5 years. Most participants (44.2%) had completed secondary school and more than a third (36.2) had university schooling as highest education. The majority (51.3 %) were reimbursed for 100% work absence and most participants (61.6 %) had still an employer. Approximately one-third had solitary pain or psychiatric related disorders, whereas about one third had a mixture of these conditions. Use of analgesics (74.1%), anti depressives (42.2 %), sedatives (33.3%) and tranquilisers (17.6%) were common. Please see table below for base line study group characteristics.

A paper describing the health situation (in Vitalis and Vitalis2) has been published.²⁵ The main findings are in line with what is presented in the table below, but further shows that the base line mental health overall was poor compared to other groups and that women born outside Sweden generally had worse mental health than Swedish-born women.

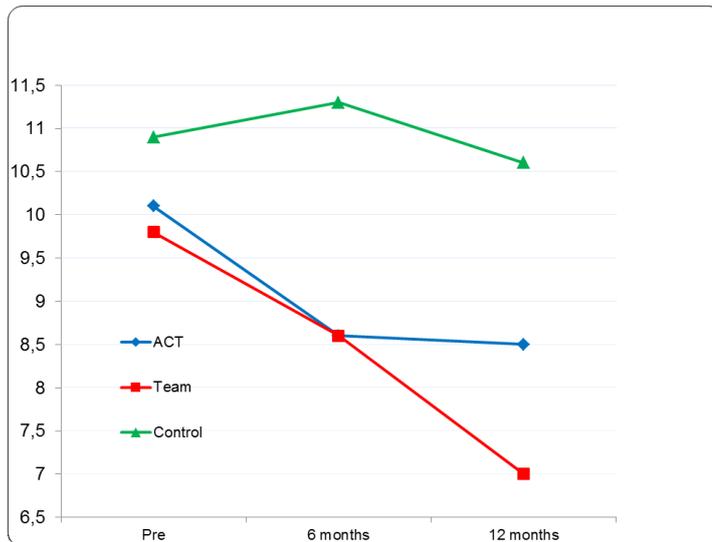
Table 1. Study group base line characteristics

	ACT	TEAM	Control	Total
Age, years (mean, SD)	47.8 (7.6)	49.9 (8.7)	47.8 (8.4)	48.5 (6.3)
Years on insurance benefits (SD)	7.6 (3.1)	7.5 (3.1)	7.5 (3.4)	7.5 (3.2)
Highest education (%)				
Primary school	14.7	23.3	21.1	19.6
Secondary school	44.0	45.2	43.4	44.2
University	41.3	31.5	35.5	36.2
Employment status (%)				
Employed	57.8	69.6	63.5	63.6
Unemployed	42.2	30.4	36.5	36.4
Type of reimbursement (%)				
Sick leave money (sjukpenning)	12.7	10.8	19.2	14.3
Sick reimburs. (sjukersättning)	87.3	89.2	80.9	85.7
Magnitude of reimbursement (%)				
25 %	14.7	11.9	12.6	13.1
50 %	22.5	32.7	30.1	28.4
75 %	8.8	7.9	4.9	7.2
100 %	53.9	47.5	52.4	51.3
Main diagnoses on sick certificate (%)				
Psychiatric	41.2	29.4	28.8	33.1
Pain	37.4	38.2	39.4	36.7
Both psychiatric and pain	26.5	32.4	31.7	30.2
Use of anti depressives	41.0	43.8	42.4	42.2
Use of tranquillizers	13.3	20.7	18.5	17.6
Use of sedatives	30.1	32.6	37.0	33.3
Use of analgesics	65.1	79.5	77.2	74.1
MADRS (only treatment groups; SD)	16.0 (9.6)	19.4 (10.5)	na	17.8 (10.2)

2. Intervention effects on mental health and pain

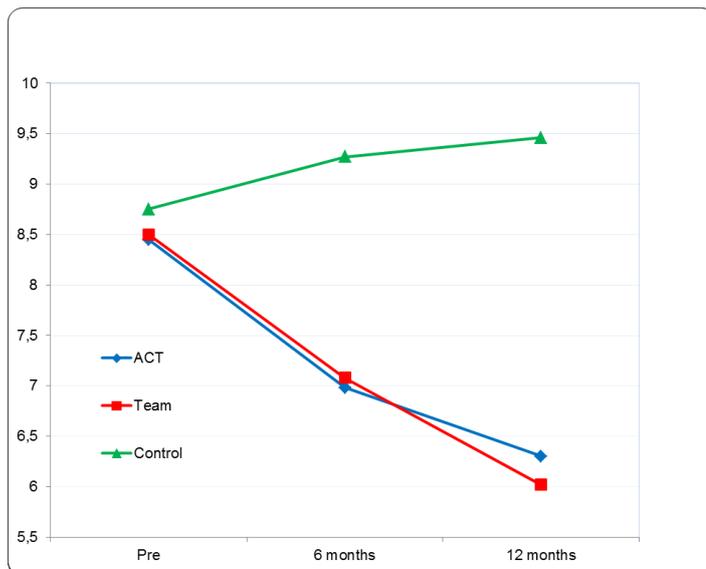
There were significant changes for the subscales, anxiety and depression in the Hospital Anxiety and Depression scale where ACT and TEAM participants improved from pre-treatment to 1-year follow in comparison to the control group; Anxiety, $p < 0.001$; Depression, $p < 0.001$, see figures 2-3

Figure 2.



Changes in anxiety (HADS) for both the ACT- and the TEAM group compared to the control group.

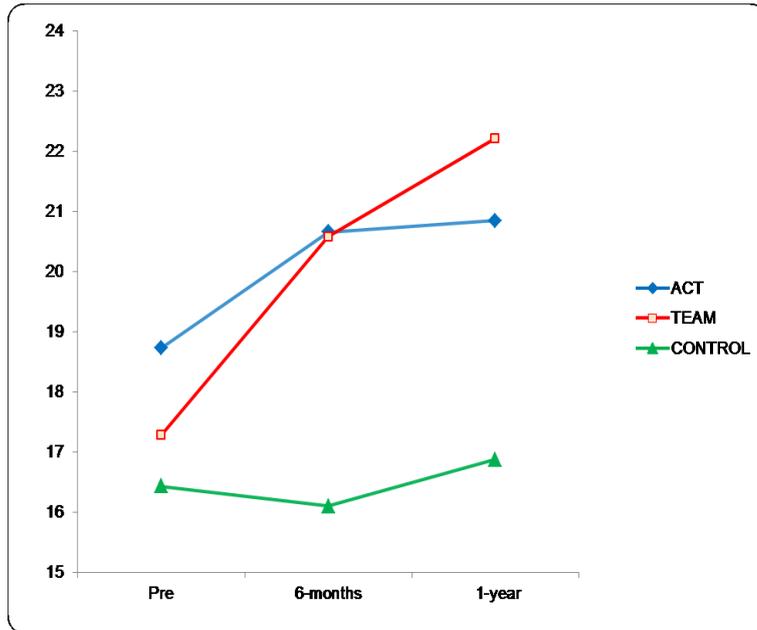
Figure 3.



Changes in depression (HADS) for both the ACT- and the TEAM group compared to the control group.

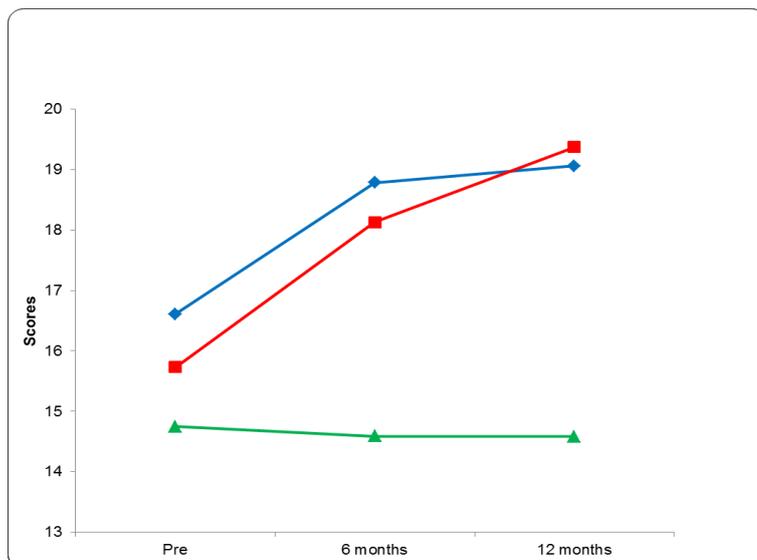
There was also a significant interaction effect between treatment and time regarding general health as assessed by the General Health Questionnaire. The TEAM condition produced significant improvement as compared to the control group, $p=0.003$. The ACT condition produced a trend of significant change, $p=0.086$ compared to the control group, figure 4.

Figure 4.



Changes in general health (GHQ) for both the ACT- and the TEAM group compared to the control group.

Figure 5.



Changes in Satisfaction with Life (SWLS) for both the ACT- and the TEAM group compared to the control group.

The Satisfaction with Life Scale showed a significant interaction effect between time and condition. The TEAM condition produced a significant change in comparison with the control group, $p < 0.001$. The ACT condition did not produce a significant change, $p = 0.145$, figure 5.

Pain intensity

Pain intensity regarding the past week did not produce a significant interaction effect. However, pain intensity regarding past three months did produce a significant interaction effect between condition and time. The ACT condition showed a significant change in pain ratings, $p = 0.014$ compared to the control group. The TEAM condition did not show a significant change in comparison to the control group, $p = 0.205$.

3. Self-efficacy in the population

Self-efficacy can shortly be described as individual's belief in his or her own ability to perform a specific action. Self-efficacy is affected by the individual's motivation, feelings, thoughts and handlings. Therefore people having self efficacy have influence over what they can do.²⁶ Self-efficacy seems to be negative related to sick-leave²⁷ and seems also be an important psychological factor for return to work after sick leave.²⁸

Self-efficacy was in this study assessed by *The General Self-efficacy Scale*, GSE.²⁹ GSE assesses the strength of an individual's belief in own ability to handle new or difficult situations and to deal with related barriers. The mean reference value for self-efficacy is around 2,9.³⁰

The purpose with this cross sectional sub study was to investigate self-efficacy among women on long-term sick leave and the relation between self-efficacy and;

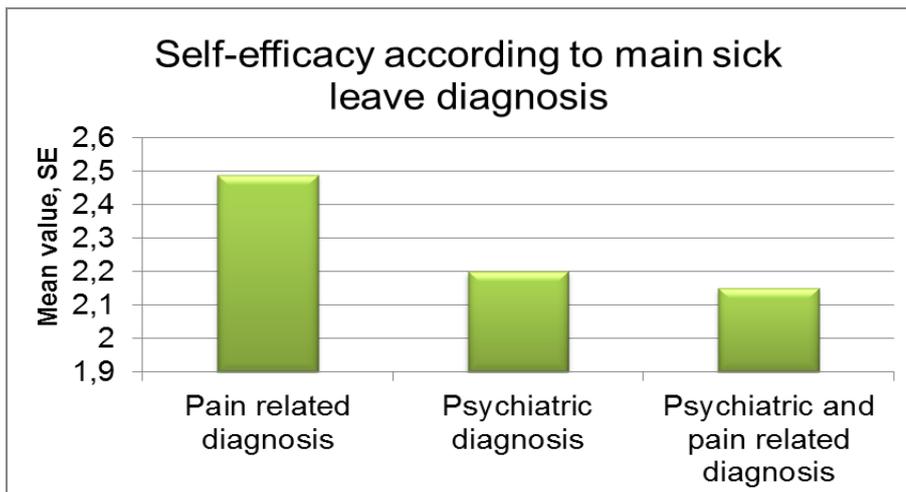
- 1) background variables,
- 2) perceived health,
- 3) physical activity,
- 4) social relations and social trust and
- 5) view of the future.

Results

Mean value of self-efficacy was 2.3 for the target group. Minimum and maximum self-efficacy score were 1 and 4, respectively.

As show in Figure 6, women with pain related diagnosis had significantly higher self-efficacy mean score compared to women with psychiatric diagnosis (2.49 respectively 2.20, $p=.003$) or both psychiatric and pain related (2.49 respectively and 2.15, $p<.001$).

Figure 6.

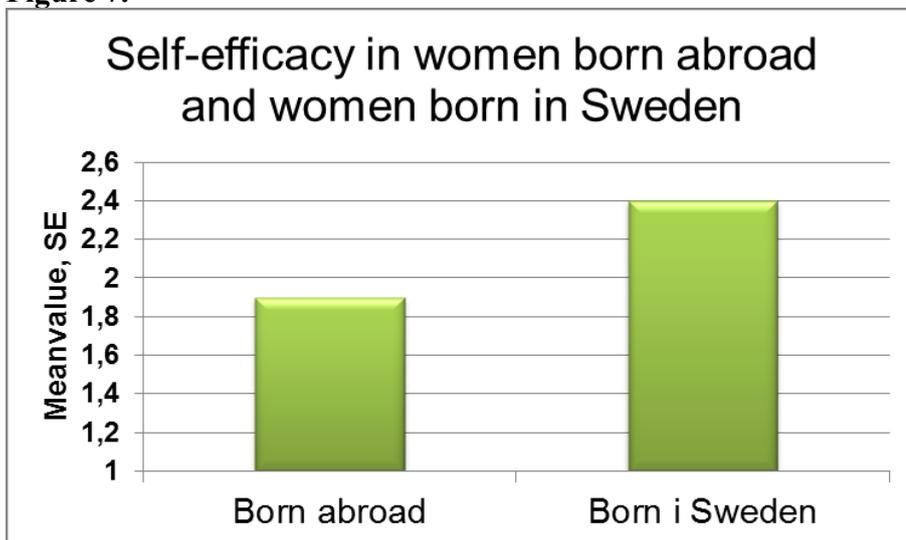


Women with pain related diagnosis had significantly higher self-efficacy mean score compared to women with psychiatric diagnosis.

No significant difference was seen in self-efficacy mean score between women with psychiatric diagnosis and those with both psychiatric and pain related diagnosis.

Mean scores for self-efficacy were significantly lower in women born abroad compared to women born in Sweden; 1.90 versus 2.40, $p < .001$.

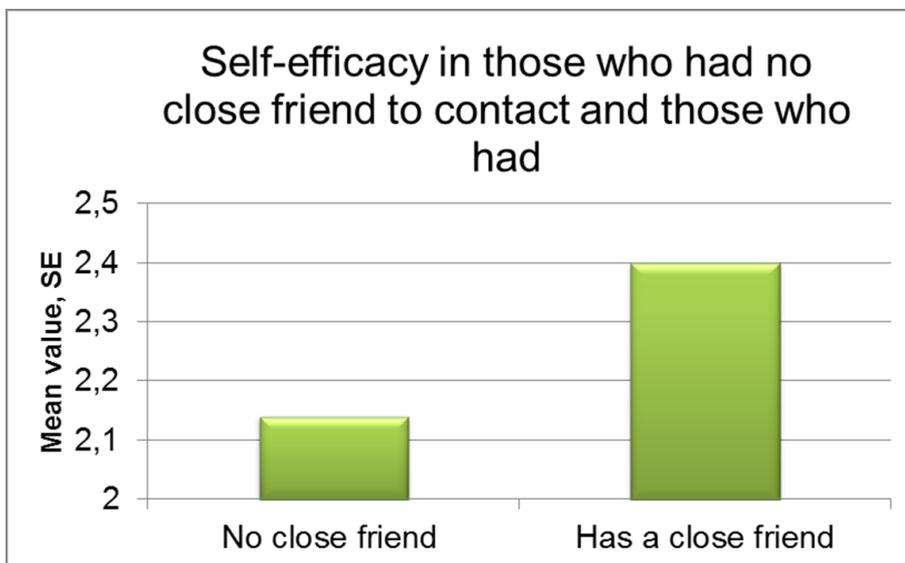
Figure 7.



Self-efficacy mean scores were significantly lower in women born abroad compared to women born in Sweden.

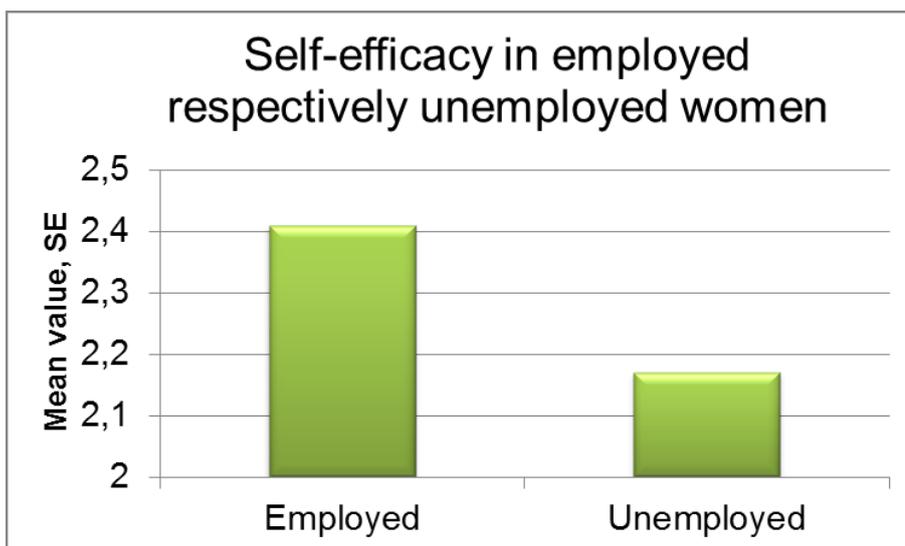
For women who had no close friend to contact, self-efficacy mean score was significant lower compared with those who had a close friend, 2.14 versus 2.40, $p < .001$.

Figure 8.



Self-efficacy mean scores were significantly lower in women who had no close friend to contact compared to those who had.

Figure 9.



Self-efficacy in employed women compared to women who were unemployed

Employed women had a significantly higher self-efficacy mean score compared to women who were unemployed, (2.41 respectively 2.17, $p < .012$), figure 9.

Table 2. Correlations between self-efficacy and background variables (n=286-337)

	1	2	3	4	5	6	7	8
1. Self-efficacy	-							
2. Diagnosis	-,028	-						
3. Age	-,041	,069	-					
4. Education level	,108	-,195**	,054	-				
5. Marital status	,017	-,065	,051	,025	-			
6. Country of birth	-,302**	,129*	,053	,083	-,005	-		
7. Time for ongoing sick leave (months)	,060	,058	,051	-,140*	,078	-,088	-	
8. Employment or not	-,137*	,127*	-,170**	-,208**	,053	,127*	,115*	-

*p<0,05, **p<0,01 (2-tailed)

There were significant relationships between self-efficacy and social relations: close friend, get support from someone, trust people and view of the future: valuation of health in six months, whether needed to be restored or not before returning to work and motivation to return to work. There was a significant negative correlation between self-efficacy and country of birth, see table 2.

Correlation analyses showed that there were significant positive correlations between self-efficacy and self-reported health. The correlations between self-efficacy and *social relations*, *view of the future* and *health* are presented in the table below.

Table 3. Correlations between self-efficacy and social relations, view of the future, health and physical activity (n=321-337)

	1	2	3	4	5	6	7	8	9	10	11
1. Self-efficacy	-										
2. Close friend	,186**	-									
3. Get support from some one	,340**	,158**	-								
4. Trust in people	,375**	,230**	,399**	-							
5. Health in 6 months	,309**	,079	,134*	,258**	-						
6. Must be restored in order to rtw	,179**	,073	,107	,091	,089	-					
7. Motivated to return to work	,319**	,167**	,158**	,210**	-,133**	,245**	-				
8. SRH	,409**	,087	,217**	,305**	-,416**	,158**	,245**	-			
9. HADS, depression	-,633**	-,181**	-,347**	-,428**	-,403**	-,133*	-,332**	-,416**	-		
10. HADS, anxiety	-,605**	-,199**	-,303**	-,388**	-,310**	-,164**	-,264**	-,389**	,685**	-	
11. Physical activity	-,208**	-,089	-,106	-,186**	-,222**	,174**	-,222**	-,151**	,196**	,174**	-

*p<0,05, **p<0,01 (2-tailed)

There were significant negative correlations between self-efficacy and depression and anxiety respectively. A negative correlation was also seen between self-efficacy and physical activity.

The multiple regression analyses showed that anxiety, depression and social support were all significant predictors of self-efficacy. These variables explained 45% of the variance in self-efficacy.

This sub study showed that attention should be given to self-rated anxiety, depression and the importance of getting support from someone. It's meaningful to highlight these factors to increase well-being, strengthening self-efficacy and facilitate return to work.

4. Intervention effects on return to work

The outcome of main interest in Vitalis was the interventions' effects on return to work (RTW), where RTW were assessed as 1) no reimbursement from public health insurance one year after project start and 2) number of reimbursed days during one year follow-up.

When an intention-to-treat analysis (ITT, all participants at randomization, n=308) was performed on the first of these outcomes, 56.5% of the ACT group, 60.8% of the TEAM group and 48.5% of the control group received NO reimbursement. Thus, there was a trend towards lesser insurance usage in the treatment groups compared to the control group, which, however, did not reach statistical significance (p-value=0.093 for TEAM vs. control and p-value=0.146 for ACT vs. control).

The figures were similar when analyses were performed only with the participants in the intervention groups who received any form (with no-shows excluded, n=269 for total group). Then 58.1 % of ACT; 59.5% of TEAM and 48.5 % of the control group received NO reimbursement at one-year follow-up. This trend did not reach statistical significance (p-value=0.143 for TEAM vs. control and p-value=0.242 for ACT vs. control).

The secondary outcome, i.e. the number of full reimbursements day during first year of follow-up, was non-normally distributed and, thus, analysed with nonparametric statistical methods. When ACT was compared to the control group, there were no statistical significant differences in either the ITT-analysis (p=0.78) or the analysis with only the persons receiving any treatment (p=0.55). There were neither any significant differences when the TEAM group was compared to control group in an ITT-analysis (p=0.38) or an analysis just comparing the ones actual treated with controls (p=0.38).

Table 4. Return to work outcomes at one-year follow-up.

	ACT	TEAM	Control	Total
Not receiving insurance, % (ITT¹)	56.9	60.8	48.5	55.4
Not receiving insurance, % (only treated²)	58.1	59.5	48.5	54.9
Fully reimbursed days during first year of follow-up. (ITT) mean (SD)/median, (iqr)	104 (116) 65 (0,197)	94 (106) 49 (0,183)	103 (110) 78 (0,195)	101 (110) 65 (0, 192)
Fully reimbursed days during first year of follow-up. Only treated. mean (SD)/median, (iqr)	101 (117) 32 (0,193)	94 (107) 49 (0,183)	103 (110) 78 (0,195)	100 (110) 59 (0,187)

1) ITT (intention to treat= all participants)

2) Analyses performed only on persons in the treatment groups who actually received any treatment/met with a health- professional

3) iqr= interquartile range, 25th and 75th percentiles

5. Predictors of success (RTW)

Predictors of RTW for the participants in the intervention groups were investigated using reimbursed days during follow-up and self reported work status at one-year follow-up.³¹ Baseline data on the participant's age, employment, sick leave duration, country of origin, motivation, HADS¹⁷, pain score³² and function score (based on Activities of Daily Living Scale for Patients with Chronic Pain³³) were used as independent variables.

At one year 36.4% of the study population reported working to some degree and 55.4% had not returned to the health insurance

Univariate analyses showed that motivation and function were negatively associated with number of reimbursed days during follow-up as well as positively associated with self-reported work status at one year. Having an employer at base line was further positively associated with self-reported work status at one year.

In the multivariate analyses higher work motivation and higher level of functioning predicted lesser number reimbursed days during follow-up. Motivation and functioning, together with having employer at baseline, further positively predicted self reported work at one year.

Thus, in this study having an employer, having high motivation and high functioning were predictors of RTW success.

6. Assessment of participants' views on the time in "Intro"

Different aspects on the participant's health and situation were collected through questionnaires during the study period. Questionnaire 2 was distributed 6-7 months after the project start, which was shortly after the participants had been in within the employment insurance's "introduction program" (intro). The questionnaire contained nine questions about their views and experiences in the intro, which were scrutinized in a masters thesis³⁴ where the experiences were compared group-wise.

The results showed that participants in the intervention groups experienced the interventions and activities in "Intro" to a greater extent to be as adapted to the needs and abilities compared to the control group. Foreign-born participants experienced that interventions and activities in "Intro" were less adapted to needs and abilities and that they were less meaningful and that the planning after "Intro" was unclear. Further, single women generally experienced their time in "Intro" as more positive and meaningful than married women or cohabitants.³⁴

One overall conclusion was that is need for a development of the existing programme "Intro" to make it more individually adapted.³⁴

6. Qualitative evaluation on project cooperation (preliminary conclusions)

The professional's experience of the rehabilitation process for individuals on long term sick absence and return to work were collected through qualitative interviews. The purpose of the present study was to describe and analyze vocational rehabilitation from the professionals view and their experience of the rehabilitation process. Data is based on thirteen interviews with the project organization (psychologists, occupational therapist, social worker and staff members from the Social Insurance Agency (FK) and Employment Insurance Agency (AF).

The preliminary analyses also showed that communication problems, processes that are not coordinated, problems with distribution of responsibility, ambiguity and difficulties to reach a common decision are factors that can discourage individuals on long term sick absence to return to work.

This part of the project will be completed in the beginning of 2015 due to parental leave. Plans are to present the above results in a peer-review-article which will also be part of an upcoming thesis.

Cost-Benefit Analysis

No formal cost-benefit analysis was planned or performed within the project by the project group. The project was, however, evaluated in terms of cost-effectiveness together with three other rehabilitation projects at the request of the government. The cost effectiveness evaluation was performed by the analytic department of the central health insurance office (Named: "Svar på regeringsuppdrag: Utvärdering av projekt som syftar till att minska sjukfrånvaron bland kvinnor". Dnr: 052379-2011, Försäkringskassan) ³⁵

This evaluation concluded that there were significant positive effects for the TEAM-treatment in Vitalis, where the participants on average had a 26% reduction in reimbursement days, compared to the control group, over a 12-30 months follow-up. The report concludes that the savings in terms of fewer reimbursed days do not cover the direct cost of the project. However, if one assumes that the results will persist longer the follow-up period (12-30 months) and also considers other potential societal savings (such as higher production, lower health care utilization and individual health benefits) the overall cost-analysis looks promising.³⁵

In this cost evaluation, performed by the central health insurance office, the TEAM-treatment was found to significant reduce the need for reimbursement days, while this outcome did not reach statistical significance within the project evaluation. We see two potential explanations. One is that a few persons withdraw their consent during the project time and were thus excluded from follow-up and evaluation. This results in a somewhat lower power in the project evaluation compared to the cost-effective analysis performed by the central health insurance office, which do not work under the same ethical legislation and may thus evaluate all participants. The other, and probably more important reason for the difference is that the cost-effectiveness evaluation used longer and differentiated follow-up periods between 12-30 months, whereas the outcome measures in the project was evaluated at 12 months for all participants. There are pros and cons with the approach used to evaluate the cost effectiveness; one clear benefit being that longer follow-up times are of is of societal interest.

One other approach to reason about cost-effectiveness is to consider the interventions effects on health. There was consistent evidence that participants receiving intervention improved their mental health substantially during the follow-up year. Arguably, better health improves the chances of RTW and lessens the need for health care utilization. Sometimes, changes in health measures, such as the EQ-5D, are used to determine cost effectiveness. This was, however, not performed in the current project.

Discussion

The main aim of the project was to facilitate RTW for the participants. This goal was not achieved. There was, however, a positive but non-significant trend for the TEAM-group compared to the control. Secondary aims included improving the participant's mental health, this goal seems to be achieved according to several different assessments of mental health.

Work rehabilitation of people on long-term sick leave may be one of the most difficult therapeutic tasks there are. The reasons why an individual is on long term sick leave is a often complex mixture of the persons physical and mental health situation in combination with other factors such as skills, education, personality, motivation, family, social context and general work and unemployment situation. Much research also points out that the longer the time a person is outside the work force, the more difficult to return. Thus, there are several potential factors that need to be assessed and addressed in a successful intervention aiming at RTW.

The participants in the current project were heterogeneous in many ways. All were having a mental health problem and/or chronic pain, but the appearance and severity of these problems differed substantially from one individual to another. Further, on average the participants had 7.5 years of long sick-leave absence. This is such a long time that most person's had adopted a view that they were not likely to work ever again. Thus, one main conclusion is that any successful RTW-intervention working with this type of patients must be individualized according to the needs the abilities of each participant. Addressing several different needs, i.e. multimodal rehabilitation, is a rehabilitation strategy proven to be an effective method in patients with chronic pain and/or mental ill health.^{13,36-39} But then again, earlier interventions are better than late.^{40,41}

The rehabilitations process involves several "agents", among the most important ones (besides the individual being rehabilitated him/herself) are the health care system, the health insurance system, the unemployment office and sometimes an employer. Other agents may be involved too. All these agents have their own agendas, regulations and cultures and there is an overall agreement that the rehabilitation process will benefit from collaboration (samverkan). The effect of good collaboration is difficult to study, as it rarely is possible to operationalize in a good way or to study its effect under controlled circumstances. Yet, according to the experience in our project the participant may benefit if representatives from the different organisations meet regularly. In this process it is important that the participant "bear" their own rehabilitation process as well as that all representatives of the organizations agree on the participant's goals and time frame for this. Unless this is done there is a substantial risk of failure. In the current project, patients receiving interventions assessed the time at the unemployment office (Introduktionsprogrammet) as better adapted

(compared to controls) to their needs and abilities, which is one measure of the positive effect of the collaboration.

Another aspect on work rehabilitation is the overall applicability of projects like Vitalis. Even if the interventions are successful, in terms of substantially increasing work motivation and willingness to work, the interventions effectiveness will still be limited by the chances of finding a job. With unemployment rates as high as during the project time (about 8%) it will be difficult to find a job even for a perfectly healthy unemployed person, needless to say much more difficult for someone trying to return from long-term sick leave. Thus, even a successful intervention may not result in significant increase in RTW. This distinction is of importance as there is increasing evidence of effect from a different rehabilitation strategy: Individual placement and support (IPS), which was described and developed by Becker & Drake 1994 and Bond 2004.^{42,43} The goal of IPS is normal (competitive) employment. IPS is based on several principles, one being motivation, but instead of first treating/training/improving skills and *then* trying to find a job, the procedure is inverse. There is an immediate and assisted search for work/employment and once that is obtained, individual support is given to both the seeking of employment and its retention. Thus the core of the IPS model is “First work, then training and education”. The IPS model has recently been deemed effective and evidence based in a systematic review.⁴⁴ The IPS model, however, is very dependent on contextual factors and has not yet been properly evaluated under Swedish conditions.

Yet another learning from Vitalis is the power of economic incentives. As it happened some participants would clearly benefit economically if returning to the health insurance system due to reimbursements from private health insurances, which naturally may decrease the willingness of remaining unemployed.

Based on our experience in Vitalis we would like to share some lessons learned for future projects involving patients with mental illness and/or chronic pain.

- Assess the severity of the underlying psychiatric disease/dysfunction and/or pain. Also good motivational interventions may be overruled by disease severity.
- Consider having motivation as inclusion criterion.
- Consider the different regulations, financial compensations and the labour market conditions in regards to unemployment and shortage of work opportunities. Is the IPS model an alternative?

Future implementation

The way Vitalis was set up, with multimodal rehabilitation including psychotherapy with ACT and a clear goal of RTW, has become the model for the rehabilitation process/program within ArbetsRehab, Akademiska sjukhuset, Uppsala.

ArbetsRehab has served as collaborating partner with Smärtrehab, Akademiska sjukhuset, from which patients with chronic pain first have been medically rehabilitated for several weeks but still are in need of work rehabilitation, and then are referred to ArbetsRehab. The work with these patients basically follows the same methods in Vitalis, which also conforms to the criteria for the county councils rehabilitation refund money (rehabiliteringsgarantin).

The methods and experience from Vitalis has also served as model for several subsequent work rehabilitations projects (such as Vitalis 2, Grön Rehab, Enter), some of which have been administered by ArbetsRehab and some where ArbetsRehab have collaborated as consulting partners.

Further, educational activities have been performed in different projects and to different collaborating partners over the years since Vitalis.

The leanings from Vitalis have been shared at the following scientific meetings.

- Andersen Å. Larsson K. and Anderzén I. Self-efficacy in women on long term sick leave. Oral presentation at the EUMASS Conference in Stockholm, September 2014.
- Anderzén I. Finnes A and Lytsy P. Vitalis – Back to Life, Back to Work. Poster session at the EUMASS Conference in Stockholm, September 2014.
- Andersen Å. Low self-efficacy in women on long-term sick leave. Poster session at Kolmården. Work and rehabilitation (3 Nordic Conference in Work Rehabilitation) Kolmården. May 2014.
- Anderzén I., Bravo K., Finnes A, Lundeén C, Toreberg E, Åbrink A, Molin L. and, Lytsy P. Vitalis – Back to Life, Back to Work. Poster at Work Stress and Health 2013: 10th International Conference on Occupational Stress and Health, Los Angeles, USA.
- Anderzén I. Finnes A. Lytsy P. Vitalis – Back to Life, Back to Work Low self-efficacy in women on long-term sick leave. Poster session

at Work and rehabilitation (2 Nordic Conference in Work Rehabilitation) Grenå, Danmark, May 2013.

- Finnes A, Bravo K, Haglund L, Lundeen C, Lytsy P, Löfgren A, Åbrink A, I Anderzén I. Using Acceptance and Commitment Therapy in the rehabilitation of women on long-term sick leave due to mental ill-health and/or pain - A randomized controlled trial. Poster. Rehsam-congress. Stockholm 2012.
- Lytsy P. Mental ill health and sick leave - Vitalis, a women project. Oral presentation national Occupational and Environmental Medicine Spring meeting, April 2014; Uppsala Concert and Congress, Uppsala.
- Anderzén I. VITALIS – back to life back to work. Oral presentation at the National Stressresearch conference Linköping and Göteborg 2012 and 2013
- Finnes A. Lundeen C. and Molin L. VITALIS – ett samverkansprojekt för sjukskrivna kvinnor. Workshop at the Conference Nordic Association for Contextual Behavioral Science (ACBS) 2012. Karolinska Institut Stockholm.

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