

**Work-related attention bias modification training and virtual reality training in
occupational rehabilitation: A multisite pilot study**

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STUDY PROTOCOL

BACKGROUND

Individuals on sick leave can be offered work-related rehabilitation with the main aim to return to part or full time work. This multisite pilot study seeks to investigate the effect of a possible new intervention called attention bias modication (ABM). Patients will be recruited from both inpatient and outpatient clinics in the regional health authorities Mid and South-East. The cognitive psychological approach will be adopted, investigating changes in the cognitive function attention during rehabilitation for patients sick listed due to psychological and musculoskeletal disorders and whether the changes can predict return to work (RTW) and employment status.

More than 600 000 Norwegians between 18 and 64 years remain outside the labour market and receive health-related benefits (Øverland et al., 2011). Psychological and musculoskeletal disorders are the most common causes of sickness absence (OECD, 2010; Brage et al., 2010; Knudsen et al., 2012; Mykletun et al., 2009) and anxiety and depression alone constitute one third of all disability pensions in Norway (Mykletun & Knudsen, 2009) and in the OECD countries (OECD, 2003). Given the prevalence of common psychological disorders such as anxiety and depression (Mykletun et al., 2009) work-related rehabilitation has proven to be a successful intervention in helping individuals with anxiety and depression and musculoskeletal disorders to RTW (Gismervik et al., 2020). The aim of work-related rehabilitation to increase the likelihood of sustainable RTW. The programmes are commonly tailored to improve the patients' level of functioning and work ability with an emphasis on physical activity, cognitive treatment components such as cognitive behavioural therapy and collaboration with the workplace. The main aim of all activities is to improve the person's self-efficacy, self-esteem and coping related to family and working life. Often an interdisciplinary team work in collaboration with the patient and are commonly made up of psychologists, physicians, nurses, physiotherapists, job specialists and sport educators.

The application of cognitive psychology to the investigation of psychological disorders has increased in recent years. Cognitive impairments and biased processing of emotional information

have been found in depression and anxiety (Beblo et al., 2011; Landrø & Andersson, 2012) and musculoskeletal and chronic pain (Apkarian et al., 2004; Landrø et al., 2013). Participation in the working life is generally considered to have beneficial effects on psychological health (Lau et al., 2012) and cognitive and emotional factors seem prerequisites for a productive working life (Fisher et al., 2017; Rodriguez et al., 2020). Occupational competence requires cognitive skills both at a personal, emotional and workplace level (Pompeii et al., 2005; Shaw & Lysaght, 2008). Preliminary research findings for the patient groups seeking work-related rehabilitation point to an association between improvements in cognitive functions and a reduction in sick leave (Johansen et al., 2019; 2021).

Attentional bias

Our attentional system is thought to be automatically drawn to particular somatic stimuli or environmental situations (Yiend, 2010). In experimental paradigms seeking to elucidate the mechanisms behind attentional processing of emotional information, the ability to recognise and recall facially, vocally and bodily expressed emotions, smells and emotion words and pictures, is investigated. One robust finding related to anxiety is that individuals vulnerable to anxious states are thought to attend to material of negative content as opposed to positive content (Williams et al., 1997; Yiend, 2010). This would involve fear-relevant material for the generalised anxiety individual and socially threatening information for the social phobia individual. What characterises anxiety is the bias or even priority in attentional resources given to threat over other stimuli. This effect has been named emotion-congruent attentional biases because individuals will often attend to emotional information and situations in the environment that matches the individuals' emotional characteristics. Similarly, depressed individuals will allocate more attention towards negative thoughts and information, which suggests that negative information is more readily recollected than positive information (Yiend, 2010). Deficits in emotion processing are thought to play both a causal and maintaining role to conditions such as anxiety and depression (Yiend, 2010).

A concept that is interlinked with attentional bias is cognitive appraisal. It plays a crucial role in emotional experience and was first proposed by Lazarus (1982). Three specific forms of appraisal have been postulated:

1. Primary appraisal (an environmental situation is regarded as being positive, stressful or irrelevant to well-being).
2. Secondary appraisal (account is taken of the resources that the individual has available to cope with the situation).
3. Re-appraisal (the stimulus situation and the coping strategies are monitored, with the primary and secondary appraisals being modified if necessary).

The concept of cognitive appraisal lends itself readily, similarly to attentional bias, to better understand the complaints reported by patients in work-related rehabilitation. The perception and experience of subjective health complaints and musculoskeletal and chronic pain have provided similar insight into attentional biases and dysfunctional appraisals as demonstrated in anxiety and depression (Brosschot, 2002; Hayes et al., 2010; Pincus & Morley, 2001). For example, it has been revealed that patients selectively process pain-related information, interpret ambiguous stimuli as pain stimuli and better remember details of pain behaviour. This suggests dysfunctions in attention (bias) and emotional states (Eccleston & Crombez, 1999; Pincus & Morely, 2001) and confirms the close relationship between appraisal, on the one hand, and experienced emotions such as anxiety, depression, pain on the other hand.

Computerised cognitive training has become a widespread intervention to improve attention and memory. Virtual reality (VR) is a measure that falls under the cognitive approach as VR technology provides the opportunity to expose participants to what hinders them from participating in working life, as well as improving attention and concentration which increases mental capacity. Previous research has shown that VR, used as an emotion-focused distraction method, reduces symptoms of anxiety, depression, fatigue and pain compared to treatment as usual (Ioannou et al., 2020). Exposure therapy using VR for social anxiety has proven to be effective both immediately after

treatment and during long-term follow-up, although long-term effects after in vivo exposure therapy appear to have a slightly better effect (Horigome et al., 2020). We assume that VR also improves rehabilitation components aimed at various forms of exposure, work training, strengthening of attention and stimulation of movement and activity despite health problems, which in the long run increases the chances of returning to work.

To target the appraisal mechanisms and emotion experiences the attention bias modification task (ABM) was developed (Browning et al., 2012). Several Norwegian studies have documented that ABM training has the potential to modify attentional biases in depression (Jonassen et al., 2019) and anxiety (Kraft et al., 2019) as well as increasing motivation for daily life activities (Kraft et al., 2019). The ABM has also been used in combination with acceptance and commitment therapy in persons reporting depressive symptoms (Østergaard et al., 2019). The combination of ABM and ACT and ACT alone similarly decreased depressive symptoms after treatment and during follow up. Cognitive training has been shown to improve the specific cognitive functions targeted in the training, however the degree to which effects generalize to working life and daily life functions is still questioned (Melby-Lervåg, 2016).

The quantitative aim of this pilot study is to compare VR training and ABM training to investigate whether the different training forms result in different results measured with work-related outcomes and cognitive outcomes. The qualitative aim of this pilot study is to investigate the patients' experiences with the usage of VR.

Objectives - quantitative

The objective of this study is to investigate whether VR and ABM training increases work ability, work-related self-efficacy, attention and reduces symptoms of depression and anxiety and consequently change an attentional bias from negative to positive stimuli. We will compare patients receiving work-related interventions + VR, work-related interventions + ABM training and work-related interventions only. We will also investigate whether positive changes in attentional bias are

associated with increased work participation. Self-reported work ability, self-efficacy, depression, anxiety and objective computerised cognitive and emotional testing will be assessed at baseline (start rehabilitation/treatment) and at posttest (end rehabilitation/treatment).

Objectives - qualitative

The objective of this part is to investigate the experiences in using VR. R&D personell will make individual interviews with five patients at each of the three clinics involved in piloting VR. The aim of the interviews will be to capture how the patients experienced the VR activity, the demands of the VR activity, how VR has influenced different aspects of health and whether VR has influenced the abilities to return to work.

STUDY PLAN

Individuals eligible for inclusion will be those between 18 – 67 years, on sick leave, work assessment allowance, disability pension receiving work-related rehabilitation or treatment at seven clinics with either an ICPC-2 (International Classification of Primary Care, Second edition) within the L (musculoskeletal), P (psychiatric) or A (unspecific disorders) categories or ICD-10 diagnosis within the F (mental and behavioral disorders), M (Diseases of the musculoskeletal system and connective tissue) or other diagnoses. *Exclusion criteria:* 1) Applying for full disability pension; 2) Unable to complete the measures and receive instructions in Norwegian.

Design and sampling

This is a non-randomised controlled experiment where we aim to recruit 20 patients from each of the six clinics involved in ABM training and up 100 from each of the clinics involved in VR. That is, 10 receiving ABM training and 10 in the control group, and 60 receiving VR and 40 in the control group. The participants will complete the questionnaires and cognitive measures one the day of arrival and on the penultimate or ultimate day of the rehabilitation/treatment. The measures will take

approximately one hour to complete at each measurement point and will not interfere with the participation in the rehabilitation/treatment.

In the qualitative part of this pilot, it is aimed to recruit 15 patients, five at each of the three clinics.

Self-reported questionnaire measures

Kvalitetsregisterkjema fra Nasjonal kompetansetjeneste for arbeidsrettet rehabilitering

Work Ability (Ahlstrom et al., 2010)

Return to work self-efficacy (Gjengedal et al., 2021; Nøttingnes et al., 2019)

Expectation about return to work (Løvvik et al., 2014)

Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983)

Computerised cognitive and emotional measures

Rapid Visual Information Processing (Cambridge Cognition, 2020) (**VR group and ABM group**)

Spatial Working Memory (Cambridge Cognition, 2020) (**VR group and ABM group**)

Stop Signal Task (Cambridge Cognition, 2020) (**VR group and ABM group**)

Attention Bias Assessment Task (Browning et al., 2012) (**ABM group only**)

Qualitative measures

Interview guide (National Advisory Unit on Occupational Rehabilitation, 2022)

Primary outcome measure

1) Work ability and expectations to return to work

2) Depression and anxiety

Secondary outcome measures

2) Cognitive and emotional performance assessed with the computerised measures



3) Total number of days on health related benefits in the year after rehabilitation/treatment

4) Patients's experiences in using VR

Virtual reality training

In collaboration with the participating clinics a systematic VR activity plan will be developed. This includes the selection of games and designing a plan that is interesting and motivating both for patients and clinicians.

Attention Bias Modification Training

The ABM task is a computerised, validated visual dot-probe procedure (Browning et al., 2012). In the original version from Browning et al. (2012) paired images of faces (the stimuli) were presented followed by one or two dots (a probe), which appeared behind one of the stimuli. Participants were required to press one of two buttons as quickly as possible to indicate the number of dots in the probe. Stimuli were pictures of emotional faces of three valences: positive, neutral, or negative (angry and fearful). The task comprised 96 trials with equal numbers of the three stimulus pair types. There were equal numbers of trials in which the stimuli were randomly presented for 500 or 1.000 milliseconds before the probe was displayed. Stimuli from two valences were displayed in each trial in one of the following pairing types: positive-neutral, positive-negative, and negative-neutral. Probes were located behind positive (valid) emotional stimuli in 87% of the trials in the training condition. Thus, when completing training, participants should learn to orient attention toward positive stimuli and in this way develop a positive attentional bias.

The aim of the current pilot study is to replace the facial stimuli with work-related stimuli categorized as positive, neutral and negative. We will follow the dosage and frequency of training applied in the other Norwegian studies (Kraft et al., 2019; Jonassen et al., 2019; Østergaard et al., 2019). Participants will use tablets with the ABM task pre-installed and will be instructed to complete

two training sessions every day from Monday to Friday for the duration of the rehabilitation/treatment.

Procedure for recruitment and testing

1. Local project representative hands out the information sheet to newly arrived participants and gives a short explanation about the project
2. The representative meets the participants the following day and asks whether he/she wants to participate. If the participants volunteers, he/she signs the consent form
3. Test 1: During the next two days the participants is administered three attention tests in front of a computer screen. It takes about 30 minutes to complete the tests. The participants also complete questionnaires about their work and health situation, as well as background information such as your age, education, marital status, type of job and work and benefit situation. It takes about 30 minutes to complete the questionnaires.
4. Test 2: On the third or second but last day of rehabilitation/treatment the participant completes the same tests and questionnaires as described above.
5. In the period between test 1 and test 2, all participants undergo VR activities or attention bias modification training on an Ipad/tablet. Each training session lasts for about 15 minutes and is carried out twice a day from Monday to Friday during rehabilitation/treatment or adjusted according to patients' needs and capabilities as well as the already existing rehabilitation programme at each participating clinic.
6. The participants in the control group complete test 1 and 2 but do not receive the added intervention described in 5.
7. R&D personell at each of the three clinics using VR will approach participants each after test 2 (sequence number 4) asking them if they would like to volunteer to take part in an interview about the experiences in using VR.



Power

A priori power calculations for F tests using G*Power (Faul et al., 2007) were performed to check which sample size was required to detect differences between groups in scores on work and health questionnaires using repeated-measures analysis of variance (pretest to posttest changes). Results indicated that with a power of 0.90, moderate effect size set at 0.25 and a two-tailed alpha level of 0.05 (Cohen, 1988), the total number of participants needed would be 44 in each group.

Study period

1 January 2022 to 1 June 2026.

Main study

This pilot study will inform whether we need to make adjustment or changes to the main study expected to commence 1 August 2024 and with particular reference to the following criteria:

- Is the main study feasible
- What changes should be made to the protocol of the main study
- What specific changes and amendments should be made to the design of the main study
- What specific recommendations to the main study are provided by the collaborating clinics and how do we deal with them and implement them in the main study

Dissemination

A project report will be published on www.arbeidoghelse.no. Publication of one scientific article.

Ethical perspectives

The project is approved by the Regional Committee for Medical and Health Research and Sikt – Norwegian Agency for Shared Services in Education and Research.



Gender issues

The participants recruited into the three groups will be matched according to gender.

Funding

This project is self-funded by each participating institution.

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This is a translation from the original Norwegian consent form, Research No. 254368, approved on November 23, 2021.

WOULD YOU LIKE TO PARTICIPATE IN THE RESEARCH PROJECT

VIRTUAL REALITY AND ATTENTION TRAINING

THE PURPOSE OF THE PROJECT AND WHY YOU ARE ASKED

This is a question to you about participating in a research project where the purpose is to get more information about how virtual reality (or virtual reality (VR) training) improves cognitive functioning. With cognitive functioning, we mean our ability to be attentive, focused, and use our memory. You are asked based on your participation in occupational rehabilitation.

Along with this information sheet, you will also receive verbal information about the project where you have the opportunity to ask questions in connection with participation. If you accept participation, you will either:

1. Receive an offer to undergo VR training in conjunction with the standard rehabilitation program to examine how VR training enhances cognitive functioning (intervention group), or
2. Receive the standard rehabilitation program without VR (control group).

The decision on whether you receive VR training will be made by the professional team.

Participating in the project will involve taking three cognitive tests at the beginning and end of the rehabilitation program to evaluate any changes in your attention skills.

WHAT DOES THE PROJECT MEAN FOR YOU?

1. Start by reviewing this information sheet. If you decide to participate, complete the consent form on page 4.
2. Test 1: Upon arrival, you'll undertake three attention tests on a computer, which will take approximately 30 minutes. Additionally, you will fill out an electronic form regarding your work, health status, and background details like age, education, marital status, job type, and benefits situation. This form should also take around 30 minutes to complete.
3. Test 2: Before discharge, you'll repeat the same attention tests and form as described in point 2.
4. If you are in the VR training group: Between Test 1 and Test 2, you'll participate in VR training sessions facilitated by a service provider. Each session will last approximately 15-20 minutes, occurring three times a week during your stay.

This is a translation from the original Norwegian consent form, Research No. 254368, approved on November 23, 2021.

5. If you're not participating in the VR training, you'll follow the activities outlined in your schedule.

We aim to compare your employment situation before and after rehabilitation. Therefore, we plan to gather data regarding your sick leave and employment status from the Norwegian Labour and Welfare Administration's database for 12 months before and after your rehabilitation stay.

POSSIBLE BENEFITS AND DISADVANTAGES

Participation in this project presents no health risks. The only obligations include completing a form, undergoing tests, and potentially engaging in Virtual Reality (VR) training. You may reflect upon your responses and test performance afterward. In case of any distress from the VR experience, a dedicated contact person will ensure access to a cognitive or psychiatric service provider, if desired. Post-VR training, it's common to experience mental fatigue. For any inquiries, contact the assigned representative at the rehabilitation center or Project Manager Thomas Johansen (contact details on page 3).

All participants will receive feedback during the second test regarding the project's effect on their attention skills. You will review your results alongside a service provider, comparing performance between the first and second tests. This collaborative discussion will help interpret what these outcomes may imply for you and your personal experience.

VOLUNTARY PARTICIPATION AND OPPORTUNITY TO WITHDRAW YOUR CONSENT

Participation in the project is voluntary. If you wish to participate, you sign the consent form on page 4. You can withdraw your consent at any time and without giving any reason. There will be no negative consequences for you or your treatment if you do not want to participate or later choose to withdraw. If you withdraw your consent, no further research will be done on your health information. You can request access to the information that is stored about you, and the information will then be provided within 30 days. You can also demand that your personal information in the project should be deleted.

The right to request destruction, deletion, or delivery does not apply if the data material or information is anonymized or published. This right may also be limited if the information has been included in completed analyses.

If you later wish to withdraw or have questions about the project, you can contact the project manager (see contact information on page 3).

WHAT HAPPENS TO THE INFORMATION ABOUT YOU?

This is a translation from the original Norwegian consent form, Research No. 254368, approved on November 23, 2021.

The data collected about you will be utilized exclusively as outlined in the project's purpose and is intended for use until June 1, 2023. Extensions for data usage and storage require approval from the Regional Committee for Medical and Health Research Ethics and other relevant authorities. You hold rights to access your registered information, correct inaccuracies, and review the security for data processing. Any complaints regarding your data handling can be directed to the Norwegian Data Protection Authority and the institution's privacy representative.

All collected data will be processed anonymously, without names, social security numbers, or any directly identifiable information, and will be linked to you via coded information. Only Project Manager Thomas Johansen, Research Manager, and the designated contact person at the rehabilitation centres can access this coded name list.

Publication of results, an integral part of research, will be conducted ensuring individual participants remain unidentifiable.

The information about you will be stored for five years after the end of the project for control reasons.

INSURANCE

Normal insurance related to the rehabilitation (the institution and the professionals' practice of their activity) applies.

FOLLOW-UP PROJECT

As a participant, you might be invited for a potential future project. Your involvement in this subsequent project would remain optional, as previously outlined under 'Voluntary participation and the opportunity to withdraw your consent'.

ECONOMY

Participating in this research project will not incur any additional costs for you, nor will you receive any compensation for your participation.

APPROVALS

The Regional Committee for Medical and Health Research Ethics (REK) has made a research ethical assessment and approved the project. The case number at REK is 254368.

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The responsibility for data protection in the project lies with the Rehabilitation Centre AiR at the Norwegian National Advisory Unit on Occupational Rehabilitation and the project manager, Thomas Johansen.

We process the information based on your consent.

CONTACT INFORMATION

If you have questions about the project or wish to withdraw from participation, you can contact project manager Thomas Johansen, phone 35 06 28 00, thomas.johansen@arbeidoghelse.no, or the responsible contact person at the rehabilitation centre.

For any inquiries related to data protection within the project, please reach out to the designated privacy officer at the rehabilitation institution.

INFORMATION ABOUT THE OUTCOME OF THE STUDY

You are entitled to receive the project results. To request a summary of the survey results in the fall of 2023, email project manager Thomas Johansen at thomas.johansen@arbeidoghelse.no or call 35 06 28 00. Project results will also be available on www.arbeidoghelse.no, www.rkhr.no and www.muritunet.no.

This is a translation from the original Norwegian consent form, Research No. 254368, approved on September 20, 2022.

DO YOU WANT TO PARTICIPATE IN THE RESEARCH PROJECT

EXPERIENCES WITH THE USE OF VIRTUAL REALITY AND ATTENTION TRAINING

THE PURPOSE OF THE PROJECT AND WHY YOU ARE BEING ASKED

As you participated in the "VIRTUAL REALITY AND TRAINING OF ATTENTION" research project during your rehabilitation stay, we're inviting you to join a follow-up study. We're interested in learning more about your experiences with using VR.

Once you've reviewed this letter, we'll reach out to discuss your potential participation and answer any questions you may have about the study.

WHAT DOES THE PROJECT MEAN FOR YOU?

1. First, begin by reviewing this information sheet. If you decide to participate, complete the consent form found on page 4. The method for submitting the form will be agreed upon.
2. Participate in an individual interview discussing your experiences with VR, which will last between 30 to 60 minutes. A researcher at your rehabilitation centre will conduct the interview with you, and together, you will arrange the specifics of when and how it will take place. The interview will be digitally recorded.

POSSIBLE BENEFITS AND DISADVANTAGES

Participation in this project doesn't pose any health risks. The only requirement is your participation in the interview. You may contemplate your responses after the interview. If the interview causes any discomfort, the research coordinator at your rehabilitation centre can arrange a discussion with a healthcare professional. If you have any questions or concerns, feel free to reach out to the research coordinator at your rehabilitation centre or project manager, Thomas Johansen (contact details provided below).

VOLUNTARY PARTICIPATION AND THE POSSIBILITY OF WITHDRAWING YOUR CONSENT

Your participation in the project is entirely voluntary. If you choose to participate, please sign the consent form on page 4. You have the right to withdraw your consent at any time and for any reason, without any negative impact on you or your treatment. If you choose to withdraw, your interview information will not be used for further research. You can request access to your stored information, which will be provided within 30 days. You can also request the deletion of your personal information from the project. However, these rights do not apply if your information has been anonymized,

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published, or included in completed analyses. If you later decide to withdraw or if you have any questions about the project, please contact the project manager (contact information can be found on page 3).

WHAT HAPPENS TO THE INFORMATION ABOUT YOU?

The information we collect about you will be used solely for the purposes outlined in the project until December 31, 2023. Any extension of this usage or storage period requires approval from the Regional Committee for Medical and Health Research Ethics and relevant authorities. You have the right to access, correct any errors in, and understand the security measures taken for your information. You can file complaints about data processing to the Norwegian Data Protection Authority and the institution's privacy representative.

Your interview will be audio-recorded and transcribed into text by an external transcriber, under a data processing agreement with the National Expertise Service for Vocational Rehabilitation. Researchers at the service and your rehabilitation centre will analyse and disseminate this data.

All data will be processed in a manner that ensures individuals cannot be identified, without any directly recognizable information such as name or social security number. A unique code will connect you to your information via a name list, accessible only to project manager Thomas Johansen and the research coordinator at your rehabilitation centre.

Publishing results, a necessary part of the research process, will be done in a way that individual participants cannot be recognized. Your information will be stored for five years post-project completion for monitoring purposes.

INSURANCE

Normal insurance related to the rehabilitation (the institution and the professionals' practice of their activity) applies.

ECONOMY

Participating in this research project will not incur any additional costs for you, nor will you receive any compensation for your participation.

APPROVALS

The Regional Committee for Medical and Health Research Ethics (REK) has made a research ethical assessment and approved the project. The case number at REK is 254368.

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The responsibility for data protection in the project lies with the Rehabilitation Centre AiR at the Norwegian National Advisory Unit on Occupational Rehabilitation and the project manager, Thomas Johansen.

We process the information based on your consent.

CONTACT INFORMATION

If you have questions about the project or wish to withdraw from participation, you can contact project manager Thomas Johansen, phone 35 06 28 00, thomas.johansen@arbeidoghelse.no, or the responsible contact person at the rehabilitation centre.

For any inquiries related to data protection within the project, please reach out to the designated privacy officer at the rehabilitation institution.

INFORMATION ABOUT THE OUTCOME OF THE STUDY

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