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Inpatient or outpatient occupational rehabilitation: what works best for whom?

Submission date
15/10/2014

Recruitment status
No longer recruiting

Registration date
20/11/2014

Overall study status
Ongoing

Last Edited
11/01/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Musculoskeletal disorders and common mental disorders are the main reasons for long-term sickness absence and disability. Many of these conditions have no or few medical explanations, and many patients are suffering from two or more disorders/ailments at the same time (co-morbidity). The main aim of occupational rehabilitation programs is to help people with such disabilities to return to work (RTW). However, knowledge regarding how well these programs work is very limited, and we know even less about which programs are best suited for which patients.
In this study, we want to compare the performance of two occupational rehabilitation programs in Norway. The main outcome is stable return to work. We will also examine if some groups of patients will benefit more from the one or the other program, and if there are any differences in costs to society in general. Several secondary outcomes will also be evaluated.
We will use a combination of methods in our data collection and analysis in order to increase our understanding of some of the mechanisms through which occupational rehabilitation programs might bring about change that support RTW. What may hinder or promote RTW among the participants during and after the occupational rehabilitation program?
The specific aims of the study are to evaluate the effectiveness of two occupational rehabilitation programs in Norway with regard to any differences in:
1. Stable return to work (work for a minimum of 4 weeks after return to work) (main outcome)
2. Sub-groups of patients that benefit more from a specific type of intervention, e.g. differences by gender, age, education, health complexity
3 The participants' trajectories in and out of work during a 5-year follow-up
4. Cost-effectiveness/utility/benefit
5. The participants' experienced quality of life
6. The participants' experienced health and work ability
7. The participants' experienced readiness for return to work
8. The participants' experienced return to work self-efficacy
9. The participants' experienced return to work fear avoidance
10. To compare return to work outcomes for the clinics with the results of a group drawn from the register of the Norwegian Labor and Welfare Service
By use of process evaluation, we will investigate possible underlying mechanisms pertaining to inpatient and outpatient occupational rehabilitation program outcomes. Our aim is also to

explain barriers and facilitators for a return to work as program providers, key stakeholders and users experience them.

Who can participate?
Employed or self-employed adults aged 18-55 who are referred to occupational rehabilitation by a physician because of musculoskeletal disorders and/or common mental health disorders, such as stress, anxiety, and depression. In addition, they must have been sick-listed for a minimum of six weeks last year.

What does the study involve?
In the first part of the study, 2014-2018, participants are randomly allocated into one of two groups. Those in group 1 receive treatment in an outpatient occupational rehabilitation clinic at Sykehuset Telemark in Porsgrunn. Those in group 2 receive treatment in an inpatient occupational rehabilitation clinic in Rauland.
In the second part of the study, 2018-2021, the participants get their treatment at the clinic they are referred to by their general practitioners without randomisation.
The programs at both clinics are comprehensive and are provided by interdisciplinary teams. The teams consist of a physician, a physiotherapist, a psychologist or a specialized nurse, and an occupational counselor/work consultant. The inpatient intervention has, in addition, a physical education teacher, a nutrition counselor, a riding instructor, and a recreation instructor.
The span of the inpatient intervention is four weeks. Each week is approximately 35 hours. The span of the outpatient intervention is three months, but the number of days and hours per week varies according to the need of the participant.
Both clinics use cognitive, behavioral, and educational approaches to increase the participants' abilities and readiness for returning to work. Interaction with relevant stakeholders is part of the rehabilitation process (e.g. the participant's employer, general practitioner, family, or NAV-consultant). The inpatient intervention is more group-based and intensive than the outpatient intervention. The outpatient intervention, on the other hand, is more individually tailored and has closer collaboration with the workplace. If the participants need follow-up after the program, the clinics collaborate with local services.

What are the possible benefits and risks of participating?
There are no risks involved in participating in the study. The participants will get a comprehensive occupational rehabilitation service whether they get the inpatient or outpatient intervention. We are not able to tell whether they would benefit more from the one or the other intervention.

Where is the study run from?
AiR - the National Centre for Occupational Rehabilitation (Norway)

When is study starting and how long is it expected to run for?
April 2014 to December 2026

Who is funding the study?
1. AiR - the National Centre for Occupational Rehabilitation (Norway)
2. The South- East Regional Health Authority (Helse Sør-Øst RHF) (Norway)
3. Kommunal Landspensjonskasse (KLP) (Norway)

Who is the main contact?
1. Chris Jensen

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2. Monica Eftedal
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Contact information

Type(s)
Scientific

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Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Project number: 2013126, Helse Sør-Øst RHF

Study information

Scientific Title
Comparing effects of two interdisciplinary occupational rehabilitation programs for people with musculoskeletal disorders, common mental disorders, or both: a nonrandomized clinical trial with a concurrent process evaluation

Acronym
STAiR

Study objectives
Added 06/03/2019:
Several earlier studies have shown that complex occupational rehabilitation programs are more effective in helping people returning to work than single interventions. However, since we compare two complex programs in this study, we do not expect to find any overall differences in return to work between the programs. We do expect that there might be some groups of patients that will benefit more from the one or the other program.

Previous:
Aims of the study described here moved to “Background and study aims” of the Plain English summary.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee REK, Norway, 03/01/2014, ref. 2011/934 REK vest

Study design
Convergent parallel design where the quantitative and qualitative research questions, data collection, and data analysis will be separate in the investigation of the main outcome but will be combined for the conclusion of the study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Available in Norwegian at request.

Health condition(s) or problem(s) studied
Musculoskeletal disorders (MSD) and/or common mental health problems, co-morbidity

Interventions
Current as of 06/03/2019:
In the first part of the study, 2014-2018, participants are randomised into one of two groups. Those in group 1 receive treatment in an outpatient occupational rehabilitation clinic at Sykehuset Telemark in Porsgrunn. Those in group 2 receive treatment in an inpatient occupational rehabilitation clinic in Rauland.
In the second part of the study, 2018-2021, the participants get their treatment at the clinic they are referred to by their general practitioners, without randomisation.

Previous:
Participants are randomly allocated into one of two groups.

1. Outpatient: Interventions and education are individually tailored.
1.1. Interdisciplinary work ability assessment
1.2. Goal setting RTW: meeting between team and patient, 1 hour
1.3. Cognitive approaches, one to one or in groups, 1-10 hours
1.4. Physical exercise, one to one or in groups, 1-10 hours
1.5. Education and lecturing regarding self-care and pain management, 2x4 hours
1.6. Individual counselling work capacity and RTW with work counselor, 1 hour
1.7. Contact with workplace and other stakeholders through meetings and phone
1.8. Collaboration with local services to offer physical exercise, cognitive therapy or follow-up at the work place if needed
1.9. Follow up by an individual coordinator.
2. Inpatient:
2.1. Interdisciplinary work ability assessment
2.2. Goal setting RTW: Group-based process work, 6 hours
2.3. Cognitive approaches, individual consultation and coaching, 4-15 hours
2.4. Cognitive approaches, group (some patients), 2-4 hours
2.5. Physical exercise, groups, 43-51 hours
2.6. Education and lecturing regarding self-care, pain management, nutrition etc., 7 hours
2.7. Individual counselling work capacity and RTW with work counselor, 1 hour
2.8. Different leisure activities
2.9. Contact with workplace and other stakeholders, usually by phone
2.10. Follow up by an individual coordinator

Intervention Type
Behavioural

Primary outcome measure
1. Stable return to work; defined as 4 weeks without relapse, register data
2. Trajectories in and out of work (full/partial work participation, sickness benefits, work assessment allowances or disability pension), register data

The participants are followed with register data until 5 years after inclusion in the project.

Secondary outcome measures
1. Cost-effectiveness/utility/benefit, SF-6D and register data
2. Quality of life; health, SF-36

3. Work ability, work ability index (WAI)
4. Readiness for return to work Readiness for return-to-work (RRTW)
5. Return to work self-efficacy, Return-to-work self-efficacy scale (RTWSE-19)
6. Return to work fear avoidance, Fear-Avoidance Belief Questionnaire

Survey data collected at baseline, 4 weeks, 3, 6, 12 and 24 months. The participants are followed with register data until 5 years after inclusion in the project.

Added 07/03/2019:
Non-randomised groups: Survey data are collected at baseline, end of program and at 6 and 12 months. Only SF-6D and WAI are used at 6 and 12 months.
7. The themes from 1.2 to 1.6 are also covered in interviews with participants. They are also interviewed regarding their expectations and evaluation of the rehabilitation program they have participated in; collaboration between key stakeholders in their RTW process; and their experiences of barriers and facilitators in their RTW process. The participants are interviewed at baseline, end of the intervention, and about 6 and 12 months after inclusion in the project.

Overall study start date
01/01/2013

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. MSDs or common mental health problems such as stress, anxiety and depression, or a combination of these. The participants may have other health complaints in addition (e.g. diabetes, coronary diseases, mild/moderate COPD)
2. In need of a service beyond what the locale health service can provide
3. Age between 18 55 years
4. At least 6 weeks sick-leave during the last 12 months related to actual health complaints
5. Fluent in Norwegian and able to fill out a questionnaire

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
680

Total final enrolment

892

Key exclusion criteria
1. Severe psychological disorders (e.g. schizophrenia and other psychotic disorder, bipolar disorder, personality disorders)
2. A progressive disorder that most likely involves a rapid reduction in work ability
3. Conditions where there is a medical contraindication for physical activity
4. Pregnancy
5. Substance addiction
6. Applying for disability pension
7. Never been working, or never been in employment

Date of first enrolment
10/04/2014

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
Norway

Study participating centre
AiR - the National Centre for Occupational Rehabilitation
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Sponsor information

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
AiR - the National Centre for Occupational Rehabilitation (Norway)

Funder Name
The South- East Regional Health Authority (Helse Sør-Øst RHF) (Norway)

Funder Name
Kommunal Landspensjonskasse (KLP) (Norway)

Results and Publications

Publication and dissemination plan
We intend to publish two protocols: one for the main study and one for the process evaluation (06/03/2019: now published, see publications list below)

Added 06/03/2019:
Publication on the main outcome is planned two years after the recruitment end date (2022 /2023). We also intend to publish several articles on secondary outcomes.

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Monica Eftedal (monica.eftedal@air.no). It is expected that all data from questionnaires, register data and interviews will be available in 2026 in anonymised form. In order to obtain the data, there must be a research project that is approved by a regional ethics committee (REC). The participants have given their consent to participate in the STAiR study, but not to share their data with other parties.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	process evaluation protocol	01/01/2018		Yes	No

Protocol article	protocol	09/02/2021	12/02/2021	Yes	No