## **STUDY PROTOCOL OPEN ACCESS**

Comparing effects of two interdisciplinary occupational rehabilitation programs for employees on sick-leave: Design of a pragmatic randomized clinical trial followed by a process evaluation Monica Eftedal<sup>1</sup>, Ulrik Gensby<sup>1</sup>, Tore Norendal Braathen<sup>1, 8</sup>, Torill H. Tveito<sup>3</sup>, M. Kamrul Islam<sup>4</sup>, Stein Atle Lie<sup>5</sup>, Gro Aasland<sup>6</sup>, Svein Kostveit<sup>7</sup> and Chris Jensen<sup>1</sup>,<sup>2</sup>

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# INTRODUCTION

# OUTCOMES

#### **METHODS/DESIGN**

Complex occupational rehabilitation programs aim to help employees return to work (RTW). However, knowledge regarding the efficiency of these programs are scarce, and randomized trials (RCTs) in complex rehabilitation programs often leave little contextual insight for occupational rehabilitation professionals striving to act upon reported effects. This RCT study compare the effects of two complex occupational rehabilitation programs in Norway, one inpatient and one outpatient. The RCT is followed by a process evaluation in order to examine the delivery of the programs, the participants' experiences of the RTW-process and their stakeholders' experiences of interaction and coordination of service delivery. The process evaluation utilizes program theory evaluation and interactive research guided by the principles of critical realism.

Main outcome is RTW. Secondary outcomes are differences in incremental cost for an averted sick leave day, cost utility/-benefit analyses, experienced health, quality of life, workability, fear avoidance for work and RTW self-efficacy. In addition: To illuminate the "black box" of occupational rehabilitation programs, and examine possible mechanisms attributed to service delivery and return to work outcomes.

### **STUDY PARTICIPANTS**

In-patient pros

Employees with musculoskeletal disorders, common mental disorders or both. Age between 18 - 55 years, on sick leave for at least six weeks during the last year. A pragmatic, randomized clinical trial (RCT) followed by a process evaluation. RTW is measured as 4 weeks of consecutive work participation. Quantitative data will be collected through questionnaires (2 years), and from national registers (5 years). 400 participants will be included. Subgroup analyses are planned. Qualitative data: a) participant observation of clinical practice, b) focus group interviews with rehabilitation team members, and c) semi-structured interviews with patients at intake and end of the program, and at 6 and 12 months follow up. Dialogue conferences with service providers and external stakeholders (employers, insurance case managers, occupational health services, and physicians).

#### DISCUSSION

Even if randomized clinical trials represent the "gold standard", they often leave little contextual insight for occupational rehabilitation profes-

**Occupational rehabilitation** 









