



## **Editorial**

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### **To RCT or not to RCT: evidence on effectiveness of return-to-work interventions**

by [Burdorf A](#), [van der Beek AJ](#)

**Affiliation:** Erasmus MC, Department of Public Health, Rotterdam, The Netherlands. [a.burdorf@erasmusmc.nl](mailto:a.burdorf@erasmusmc.nl)

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## *To RCT or not to RCT: evidence on effectiveness of return-to-work interventions*

The randomized controlled trial (RCT) is considered the gold standard in evaluative medical research for drawing causal inferences about the effects of the intervention under study. For several reasons, in occupational health research, an RCT is neither always the best study design nor the most feasible option. Alternative study designs are increasingly being used in situations of complex interventions, whereby multiple stakeholders are involved in a varying context (1). These designs, which mimic natural experiments, support innovative research in occupational health as they offer a new platform to examine the effectiveness of interventions combining an individual approach with workplace adjustment (2).

A typical example is the area of return to work (RTW). A recent review on interventions to manage musculoskeletal-related sickness absence showed that various behavioral interventions have been evaluated in RCT. In general, person-oriented intervention studies can easily be randomized. For workplace-oriented interventions, this is less straightforward. It is not surprising, therefore, that considerably less RCT have been able to include workplace adjustments as workplace interventions (3). Typically, those RCT have small study populations and are limited to a few work organizations. The balance between the rigorousness of an RCT and a large-scale observational study has been nicely illustrated by studies on the effects of partial sickness absence in Finland. The RCT consisted of subjects with musculoskeletal disorders from six enterprises comparing 31 workers in the intervention group with 31 workers in the usual-care group (4). The observational study on register information with propensity score matching compared over 1000 subjects in the intervention group to >25 000 subjects in the usual-care group (5). Although the latter study has higher risk of bias, the RCT was so small that generalizability may be questioned. Thus, there is a clear need to make better use of existing possibilities of routinely collected data for evaluating the effects of particular interventions.

In this issue of the *Scandinavian Journal of Work, Environment & Health*, Bethge (6) presents an elegant example of how register-based information can be utilized to determine the effects of graded RTW (GRTW). In Germany, this program is offered to patients who are unable to return to work at full capacity in their regular job immediately after clinical rehabilitation has finished. Several factors contributed to the decision that a randomized study was not possible. First, this GRTW service was introduced and implemented nationwide before proper scientific evaluation on its effectiveness was conducted. As researchers, we have the choice to either gnash our teeth about such developments and rue missed opportunities for evidence-based policies or try to take advantage of the large-scale implementation by studying effects in an observational study under routine conditions. Second, the GRTW service requires agreement and consent from the patient, the employer, the general practitioner, and the occupational physician. This inevitable procedure will remove one of the key advantages of an RCT, ie, blinding of the patient and all persons involved in treatment. Third, a related problem is that it will be hard to convince everyone that, after consent has been given by all parties involved, the randomization procedure will determine who will get the GRTW service and who will not get this therapeutic work resumption. The author turned the disadvantage of not being able to conduct an RCT into the advantage of carrying out a large observational study with multiple outcome measures over a prolonged follow-up period through linkage of different registers.

The Bethge study presents some important results. In the GRTW intervention group, there was less sickness absence (>50 days difference compared to usual care) during the 3-year follow-up period. In addition, the risk of a disability benefit decreased by 40%. Through the linkage with other registered-based

information, it was also shown that the GRTW group had a €4000 per year higher income, an important observation not often reported in occupational health studies. Through the large study population of 1875 persons in the intervention group, sufficient statistical power was available for several subgroup analyses. There were no differences across diagnostic group, suggesting that a graded RTW approach may be similarly beneficial for workers with musculoskeletal disorders, mental disorders, and cancer. The relevance of this finding cannot be underestimated, since it would have been virtually impossible for any intervention to conduct a sufficiently large RCT, or alternatively four RCT in different patient groups.

Bethge stated that GRTW is “a therapeutic measure that aims to test and practice work capacity at the workplace” (6, p272). The effects of GRTW have been studied more often, using a range of different terms for more or less the same intervention: partial or part-time sick leave, adaptation in working hours, graded work exposure, and partial or therapeutic work resumption. A cohort study in six countries demonstrated that GRTW was the most commonly applied intervention among workers who were sick-listed due to low-back pain (7). Almost half of all cohort participants (46%) were offered GRTW. A study evaluating the effects of GRTW using an instrumental variable method indicated that it improved the probability of recovery to full work capacity among workers on sickness absence due to musculoskeletal disorders (8). Another study, applying econometric models to analyze combined survey and register data, also showed this beneficial effect for GRTW on return to regular working hours, irrespective of the cause of sickness absence (9). For employees sick-listed due to mental disorders, however, econometric models revealed that GRTW was not effective in promoting return to regular working hours (10) or that GRTW was only effective after >60 days of sickness absence (11). These findings correspond to a Cochrane review on workplace interventions to prevent work disability among workers on sick leave, which also showed better effects for workers with musculoskeletal disorders than for those with sickness absence due to mental disorders or cancer (12). From this perspective, the results of Bethge were more hopeful in that, with the exception of persons with cardiovascular disorders, GRTW was found to be beneficial for those with musculoskeletal disorders, mental and behavioral disorders as well as cancer (6).

In conclusion, Bethge’s observational study presents evidence that (i) gradual RTW is a method to be used across most chronic diseases and (ii) timely attachment to one’s job will support workers to remain productive in their regular job and have a higher income. The latter is certainly an uplifting message for the reader of this journal. Often our studies focus on the adverse effects of work on health. The study demonstrates that for many workers with health problems, being at work promotes health and wealth!

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Alex Burdorf  
Erasmus MC,  
Department of Public Health,  
Rotterdam,  
The Netherlands.  
[E-mail: a.burdorf@erasmusmc.nl]

Allard J van der Beek  
VU University Medical Center,  
Department of Public and Occupational Health,  
The EMGO+ Institute for Health and Care Research,  
Amsterdam, The Netherlands.  
[E-mail: a.vanderbeek@vumc.nl]

