



Trial participant representativeness compared to ordinary service users in a work rehabilitation setting



Simon Øverland ^{a, b, *}, Astrid Grasdal ^c, Silje Endresen Reme ^d

^a Department of Public Mental Health, Norwegian Institute of Public Health, Norway

^b Department of Psychosocial Science, University of Bergen, Norway

^c Department of Economics, University of Bergen, Norway

^d Uni Health, Uni Research, Bergen, Norway

ARTICLE INFO

Article history:

Received 28 July 2015

Received in revised form

20 November 2015

Accepted 2 December 2015

Available online 17 December 2015

Key MeSH terms:

Pragmatic clinical trial

Depression

Anxiety

Disability

Sick leave

ABSTRACT

Background: Study representativeness is a major concern for generalizations from trials. The extent of the problem varies with study design and context. There is a strong emphasis on developing interventions to help people remain in the work force despite mental illness. We need to know if results from upcoming trials in this area are valid for those that later might receive the services.

Method: The AWaC trial was a multicenter RCT conducted at six different treatment centers (n = 1193). After the trial was over, the centers were upheld and run as ordinary services. At that time, we surveyed 80 ordinary service users with the same baseline questionnaire as used in the trial, and compared them with those who participated in the trial.

Results: There were a higher proportion of people with the highest level of education (4 years or more at university/college) in the post-trial comparison sample. This sample also reported to be “dissatisfied” with their job more often, but rated their chances for return to work as “bad” less often than the ordinary trial participants. No further significant differences between the two samples in any of the other education categories, or for any of the other demographic, health or work related comparisons were found.

Discussion: Participation bias is likely to depend on study context, but in the setting of a trial to help improve work participation among people who struggle with common mental disorders, the trial participants were overall very similar to those who sought the same services as ordinary practice.

© 2015 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

Running a sound clinical trial is demanding, but implementation of results in the wider population present numerous layers of challenges. Trials commonly employ strict inclusion and exclusion criteria to maintain experimental control and secure internal validity [1]. Furthermore, participation in trials is based on informed consent, and sub-sections of the population might be more or less inclined to participate [2]. Participant selection and bias may arise from criteria definitions and selective participation, and determine generalizability of trial results outside the study sample [3,4].

For clinical trials in mental health, researchers have tried to quantify this problem by assessing ordinary help-seekers with

common study inclusion criteria. Of 346 patients with depression, Zimmermann et al. found that only 1/6 would qualify for inclusion in antidepressant efficacy trials employing common criteria [5]. The eligible population also differed from the non-eligible on demographic, clinical and psychological profiles [6]. In a study of actual trial recruitment, 7 out of 8 who volunteered, were turned away due to pre-defined criteria for study inclusion [7]. In a Dutch study comparing participants in RCT's for major depressive disorder to patients attending ordinary care, the trial participants were much more likely to be employed [8].

The core question of whether results from trials can be generalized to a larger population does not seem to converge to one general conclusion, but vary with the context of the trial. Some studies argue that their trial results can represent real-life effects outside the trial settings [1,9], whereas others prompt careful consideration of generalizability [5,6,10,11].

Sickness absence and long-term work disability is a major issue in occupational medicine, and we find it is likely that the number of

* Corresponding author. Department of Public Mental Health, Norwegian Institute of Public Health, Kalfarveien 31, 5018 Bergen, Norway
E-mail address: simon.overland@fhi.no (S. Øverland).

trials to prevent long-term sickness absence and disability pension from mental illness will increase. In a recent pragmatic trial in this context [12], we defined exclusion/inclusion to allow recruitment of participants who also would be likely to seek the intervention outside the trial. In this paper, we examined if we were successful, and hypothesised that the participants in our large multi-center RCT did not differ substantially from those who attended the same services outside the setting of a trial.

2. Methods

2.1. Context

The context of the AWaC-trial, from which these data were generated (pre-trial registration details at ClinicalTrials.gov, registration number: NCT01146730) can be found in the main effect study and its protocol [12]. In short, the trial tested the effectiveness of the At Work and Coping intervention (AWaC) vs. usual care in helping people who struggle with work participation due to mild to moderate common mental illnesses participate in working life.

2.2. Study samples

This analysis is a comparison of a trial sample and a post-trial comparison sample.

2.3. Trial sample

Trial participants were mainly recruited through referrals from the Norwegian Welfare and Labor Administration, GPs and self-referrals. The main inclusion criterion was that common mental disorder was seen as the main reason why the person struggled with work participation. The accepted age span was 18–60 years, and potential participants had to express a motivation to return to/stay at work. People were excluded if they reported other reasons as the primary cause of work participation problems (e.g. somatic, social, economic and work-related issues), no motivation/desire to work, suffered from severe psychiatric disorders, had high suicide risk or a current substance abuse problem, or was engaged in psychotherapy elsewhere already. Pregnant women were excluded, as were people unable to read or write in Norwegian.

Potential participants were informed about the project, and screened for inclusion and exclusion criteria at the centers. Eligible and willing participants signed the informed consent and completed the baseline questionnaire. After random allocation, participants were written about the outcome and the intervention group were given a date for their first session.

1416 potential participants were referred and considered for inclusion. Of these, 197 did not fulfill the inclusion criteria, 17 did not consent to participate, and 9 withdrew their consent and required data deletion (2 from the intervention group and 7 from the control group). In total, 1193 participants entered the trial and were randomized.

2.4. Post-trial comparison sample

The sub sample of 80 persons was recruited after the completion of the trial, and we obtained specific ethical approval for this data collection. The data were collected at the 6 centers that were part of the multicenter trial in June 2012, when the centers no longer recruited or evaluated potential patients for trial inclusion, or had trial participants in treatment. New cases enrolled at the centers over a period of one month were invited to participate. Like the trial participants, they came to the centers after referrals from the Norwegian Welfare and Labor Administration, their GP, self-

referrals or through other channels. We do not have the exact figures on how many attended the centers during June 2013, but the final n of 80 exceeded the average number included in the trial per month (total $n = 1193$ included over a period of 18 months equals an average of 67 participants per month). Those who were willing to participate in the post-trial sample, were asked to complete a shortened version of the baseline questionnaire used in the trial.

2.5. Statistical comparisons

The aim of this study was to compare the trial participants with those who found their way to the same treatment centers after the trial was over. We did this by comparing the two samples in terms of self-reported demographic characteristics and scores on key health variables using chi-square tests for categorical variables and t -tests for continuous variables.

2.6. Ethics

The trial and the post-trial comparison survey were both approved by the regional committee for medical research and all participants provided informed consent.

3. Results

There was no overall difference between the samples on any of the variables. When examining single response levels separately there was a higher proportion of people with the highest level of education (5 years or more at university/college) in the post-trial comparison sample. They also reported to be “dissatisfied” with their job more often, but rated their chances for return to work as “bad” less often than the ordinary trial participants. Beyond that, there was no significant difference between the two samples in any of the other education categories, or for any of the other demographic, health or work related comparisons (Table 1).

4. Discussion

The data supported the hypothesis that those who participated in a pragmatic multicenter randomized controlled trial were comparable to those who attended the same services outside the context of a trial in terms of self-reported health and demographic characteristics.

There are limitations to our study that should be considered. There could of course be a common self-selection process in both these samples, where those unwilling to participate in research at all – both concerning the trial and the post-trial comparison – share the same characteristics and health status. Anecdotal evidence however suggested that disapproval against randomization was an important hindrance to participation for individuals, but also their referring doctors or case-managers.

By logic of multiple testing, one in twenty comparisons should appear significant despite no true underlying difference. Here, we did a total of 35 comparisons, and found three statistical differences between the samples when directly comparing individual scores on a scale, despite no overall difference for those scales. Thus, even in the presence of these statistically significant differences between the samples, we argue these are insufficient to reject our initial hypothesis of similar samples.

Anecdotally, the treatment centers reported increased referral rates after the trial inclusion period, which resonates with the higher number of participants in the post-trial comparison sample compared to the average inclusion per month during the trial. Individuals, case-managers and general practitioners could have been skeptical to participation as trials are more uncommon in this

Download English Version:

<https://daneshyari.com/en/article/2498717>

Download Persian Version:

<https://daneshyari.com/article/2498717>

[Daneshyari.com](https://daneshyari.com)