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by

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A web-based tool to support shared decision-making for people with a psychotic disorder – a randomized clinical trial and process evaluation

TITLE

1a-i) Identify the mode of delivery in the title

"A web-based tool to ... "

1a-ii) Non-web-based components or important co-interventions in title

Not applicable. We do not use co-interventions.

1a-iii) Primary condition or target group in the title

"...for people with a psychotic disorder ..."

ABSTRACT

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

"Patients in the intervention condition (n=124) were provided an account to access a web-based information and decision tool aimed to support patients in acquiring an overview of their needs and appropriate treatment options provided by their mental health care organization."

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

"Patients were given the opportunity to use the web-based tool either on their own, at their home computer or at one of the computers of the service, or with support of an assistant. "

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

"Patients in the intervention condition (n=124) were provided an account to access a web-based information and decision tool ..."

1b-iv) RESULTS section in abstract must contain use data

"Seventy-three patients completed the follow-up measurement and were included in the final analysis (response rate 29%). Results show that almost half of the patients who were provided access to the web-based decision aid did use it, and the majority of them used its full functionality. However, no differences were found between intervention and control condition on perceived involvement in medical decision-making (COMRADE risk communication F(1) = 0.422, p = .518; COMRADE confidence in decision F(1)= 0.086; p = 0.770). In addition, results of the process evaluation suggest that the intervention did not optimally fit in with routine practice of the participating teams. "

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

"However, results of this paper could not support the assumption that the use of electronic decision aids increases patient involvement in medical decision-making. This can be partly explained by a weak implementation of the study protocol and a low response rate. "

INTRODUCTION

2a-i) Problem and the type of system/solution

"This paper reports on a randomized clinical trial and process evaluation of a web-based intervention to facilitate shared decision-making, with or without assistance, in people with psychotic disorders. "

2a-ii) Scientific background, rationale: What is known about the (type of) system

"Shared decision-making in mental health care has been dubbed an ethical imperative [1]. Since the rise of recovery-oriented medicine, patients have been acknowledged as experiential experts and equal partners in communication with clinicians. Research has shown that people with severe and persistent mental disorders are no exception. People with psychotic disorders are able and willing to participate in medical decision-making [2, 3]. However, the desire for participation is greater than the amount of participation they actually experience [4, 5]. A range of obstacles are hampering successful implementation. Most clinicians believe in the benefits of shared decision-making, but time constraints and a large number of clinical responsibilities retain them from practicing it [6, 7]. Moreover, patients may not be used to actively participate in medical decision-making and they sometimes lack access to medical information that is easily intelligible [8].

Therefore, Drake and Deegan [9] have stressed the need for decision aids and support centers to ensure the development of an infrastructure that facilitates the practice of shared decision-making. Several initiatives have been developed in this area. For instance, in Germany, Hamann et al. [3] investigated the effectiveness of a shared decision-making intervention with a printed decision aid for inpatients with schizophrenia. They found that patients using the decision aid, compared to a control group that received care as usual, had better knowledge about their disease and had a higher perceived involvement in medical decisions [3]. Recently, a special case was made for electronic decision aids [10], as they have various advantages over paper-based decision aids, such as presenting personalized information based on smart algorithms. So far, three electronic decision aids have been developed and investigated to support shared decision-making in the treatment planning for people with severe mental disorders, but the results are inconsistent [11, 12]. A pilot study by Deegan et al. [11] showed that outpatients were able to work with a web-based program to support shared decision-making on psychopharmacological consultation. Patients used the program on computers at the clinic where experiential experts were available for assistance. Two small-scale randomized clinical trials were conducted [12, 13]. The first trial showed that patients were able to electronically make up their own care plan, but there was no difference between intervention and control group on satisfaction with the care planning process, which was the primary outcome [12]. The second trial reported that a web-based support system encouraging patients to discuss their current status and treatment with their clinician resulted into patients being more verbally active during health visits [13].

More evidence is needed to determine whether electronic decision aids are helpful in clinical practice, and lead to increased patient involvement and better outcomes. In addition, more information is needed on what proportion of patients is willing and able to work with web-based decision aids, and in what form (with or without assistance, using their own computer or one at the clinic)."

METHODS

3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio

"Our aim was to investigate this intervention in a naturalistic setting, meaning that all eligible patients were included in order to be able to determine how many of them would actually use the decision aid. "

Patients in the intervention condition received care as described in the local disease management program for the treatment of people with psychosis plus they were offered the opportunity to make use of the web-based information and decision tool (see Multimedia Appendix 1). This tool is meant to support patients in acquiring an overview of their care needs and of the treatment modules provided by their mental health care organization. The tool functions as a website consisting of three tabs and a homepage. The homepage briefly explains the aim and procedure of the website. The first tab presents a questionnaire about care needs, based on items of the CANSAS-P. The second tab offers a digital catalogue with descriptions of treatment modules dynamically linked to the outcomes of the questionnaire in the first tab. For instance, a reported need for more information about symptoms and medication use was linked to information about the module psychoeducation, while a reported need on items about living a meaningful life and doubts about the future was linked to a module about loss and longing. In addition to this selection of modules, patients also had the opportunity to view all available treatment modules, irrespective of the questionnaire outcomes. The information about the available modules in the catalogue included an overview of its content and duration, a description of problems/symptoms the treatment module is usually indicated for, names, functions and pictures of clinicians involved, a short story by a patient who tells his/her experience with the treatment module, and, if available, a brief interview with a clinician who tells about his/her experience with the treatment module (advantages, disadvantages, motivation to provide the treatment, etc.). The third tab presents a list of all treatment modules in a checkbox format. The content and design of this web-based tool was based on an earlier usability study.[14] During the development process, the content of the tool was validated by clinicians and patients. This content was 'frozen' during the trial. Patients using the web-based tool were asked to look through the treatment modules and to choose the modules of their preference by ticking the according checkboxes. Patients could print the checkbox form and take it with them to the treatment plan evaluation session to discuss it with their clinician.

Control condition:

"Patients in the control condition received care as usual, as described in the local disease management program for the treatment of people with psychosis. Treatment modules were initially chosen by a clinician in accordance with a treatment path that a patient entered based on the staging of the disorder (first episode or stabilizing/rehabilitation phase), clinician rated scores on the HoNOS and patient rated scores on the Camberwell Assessment of Need Short Appraisal Schedule (CANSAS-P). During a treatment plan meeting, clinicians informed patients about the indicated treatment modules, and also discussed alternatives. A final decision was to be made in a process of 'shared decision-making' (which was not further specified in the disease management program). "

"No further instructions were given about the optimal timing of frequency regarding the use of the decision aid."

"Patients were given the opportunity to use the decision aid either on their own, at their home computer or at one of the computers of the service, or with support of an assistant. Furthermore, an assistant was available by phone for help for three days a week. "

Not applicable.

Not applicable.

"Per protocol analyses also showed that ..."

"In an additional analysis, patients in the intervention condition who received the allocated intervention (n=30) were compared to patients in the intervention condition who did not receive the allocated intervention (n=10)."

18-i) Subgroup analysis of comparing only users

Our primary analysis was an intention-to-treat analysis. We did add a per protocol analysis, but only secondary.

19) CONSORT: All important harms or unintended effects in each group

See below.

1.

