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Connecting needs and care in psychosis

Roebroek, Lukas

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Connecting needs and care in psychosis

An illustration of decision support in psychosis care

Lukas Roebroek

Connecting needs and care in psychosis: an illustration of decision support in psychosis care

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Connecting needs and care in psychosis

An illustration of decision support in psychosis care

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by

Lukas Olivier Roebroek

born on 10 December 1985

in Nijmegen, The Netherlands

Supervisor:

Prof. S. Castelein

Prof. P.A.E.G. Delespaul

Co-supervisor

Dr. J. Bruins

Assessment committee

Prof. M.A.G. Van Offenbeek

Prof. W. Cahn

Prof. C.L. Mulder

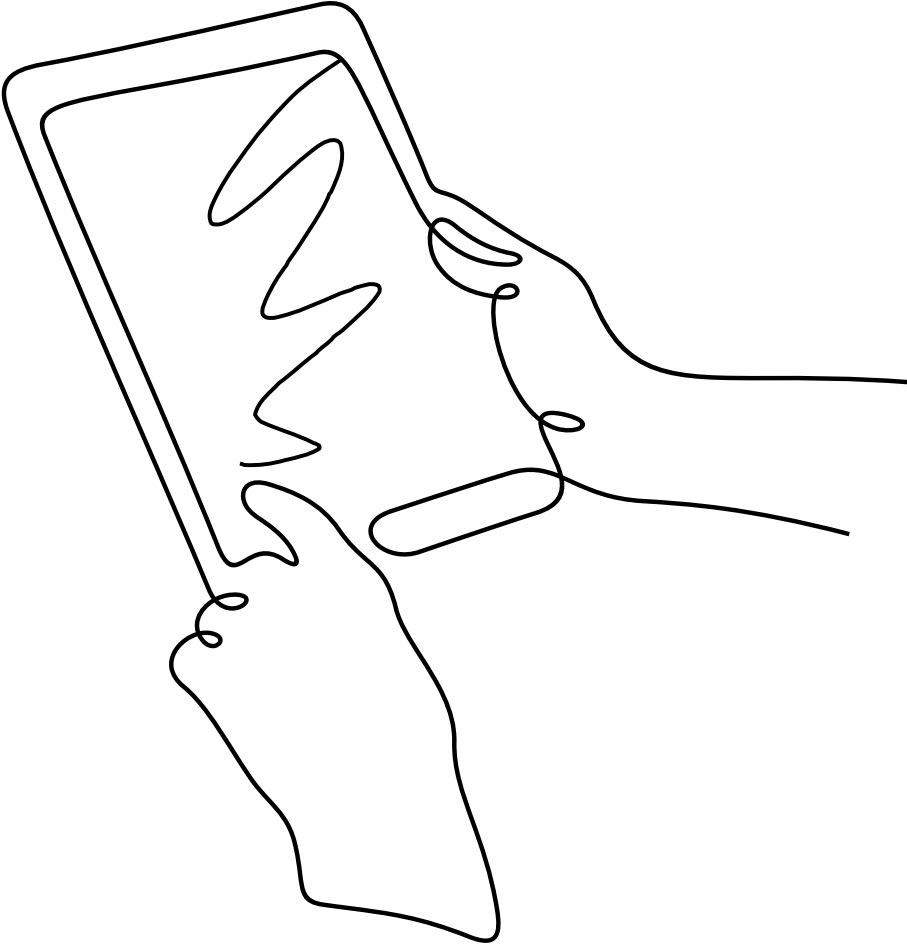
Paranymphs

Steven de Jong

Jasper Scholten

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Chapter 1

General Introduction

A digital transformation in healthcare: the promise of decision support

In 1993, David Gelernter, a professor in computer science at Yale University, wrote a book called: *Mirror worlds, or the day software puts the universe in a shoebox* (1). In this compelling book, he predicted that computers through interconnected systems would start to transform every part of society in an exponential fashion. Nearly 30 years later these predictions are reiterated by the World Economic Forum which has stated that we are on the brink of a fourth industrial revolution, characterized by a fusion of technologies integrating the physical, digital and biological domains (2). This digital revolution is now spreading throughout our healthcare systems with e-health, electronic patient's records, experienced sampling, smart wearables, machine learning, artificial intelligence and telemedicine among others (3). Decision support in the form of computerized clinical decision aids (CDAs) are also gaining popularity in various medical disciplines (4). These tools exist in many forms and are designed to assist patients and clinicians in making healthcare decisions (4). There is growing evidence demonstrating the efficacy of CDAs in clinical decision-making (5). Algorithms at this point in time are subject to errors, at the same time there is also a substantial body of evidence demonstrating the fallibility of human decision making. The medical field of psychiatry, in which a special human touch is considered an important aspect, has until recently remained somewhat immune to this digital transformation. Although e-health, blended care and virtual reality are making headway in psychiatry, research on decision support and CDAs is still scarce, especially when it goes beyond medication support (6,7). A recent systematic review identified 56 studies relating to decision support in a mental healthcare setting (6). The majority of the tools in these studies were still in the developmental stage without any exposure to real-world interactions. Only four studies investigated a fully functioning tool in a clinical setting. But even after successful experimental trials, implementation of CDAs in routine practice remains challenging (8,9). Therefore, it is fair to say that decision support in mental healthcare is still in its infancy. The main aim of this dissertation is to examine the effects of decision support and its potential future in psychosis care.

The ethical imperative of shared decision-making in psychosis care

People with psychotic disorders are often faced with complex problems requiring long-term treatment in different areas of their life, such as psychiatric or physical issues, lack of daytime activities, work or study, loneliness or personal safety (10). Some of these issues are difficult to treat, therefore remain unresolved and can be considered care needs that persist over time (11-13). Identifying and accommodating these needs with care focused on long-term disease management requires close cooperation between mental healthcare institutes and social organizations (14). From a recovery point of view, finding adequate and optimal treatment is often a long-term iterative process between patient and clinicians. Most treatment decisions for people with a psychotic illness do not have a clear best option, but rather involve complex trade-offs. For example when deciding on pharmacological interventions which are known to cause cardiometabolic risk factors, tardive dyskinesia or sexual functioning disorders (15). Interventions don't always have predictable outcomes and by exploring different options the resilience and motivation of patients can grow. Therefore, it becomes an ethical imperative for these decisions to be considered by well-informed patients and skilled healthcare professionals on the basis of evidence worth exploring. This information can be used to reach consensus on the perceived most beneficial treatment plan in accordance with personal preferences of patients.

Historically, decision-making in psychiatry has long been based on a paternalistic model in which clinicians held most of the knowledge and decisional power (16). In recent decades, there has been a gradual transition towards a more ethical and patient-centered informed choice model of shared decision-making (16). The term shared decision making (SDM) was first clearly conceptualized by Charles and colleagues in 1997 as: "a process most relevant in situations where important decisions are made at key points in the treatment process, when multiple treatment options with different benefits and risks are available and when uncertainty exists" (16). This process intends to increase the exchange of information and strengthens the decisional position of people with a psychotic illness in mental healthcare (17). There has been a strong increase in SDM research in recent years (18), which has sparked the interest of healthcare policy makers around the world (19). In 2011, the Dutch government called for nationwide structural

implementation of SDM in the Dutch healthcare system (20), but this is easier said than done as its implementation in clinical practice is slow and difficult (21). This is mostly due to a lack of knowledge, applicability or perceived utility and because of environmental factors such as time pressure or organizational constraints (21). Several interventions to increase SDM currently exist, such as 'problem definition and agreement'-training for healthcare professionals or training for patients to increase their involvement and autonomy in the decisional processes (22). Another option that gained popularity are CDAs. These tools have shown to foster SDM in various medical fields (5), but with little research and real world-application it remains unknown if they can do the same in mental healthcare settings.

Is routine outcome monitoring used to its full potential?

More and more patient data are collected systematically by mental healthcare institutions. It can be challenging for clinicians to make optimal use of the available data for treatment, diagnostics, disease management or prevention (13,23). Routine outcome monitoring (ROM) is often used as a systemic approach in the assessment of patients' health and wellbeing. ROM results can serve different purposes at an individual, team or organizational level. In recent years, the use of ROM for benchmarking was lively debated in the Dutch mental healthcare system (24). Although the benefit of benchmarking services is open for debate, a recent meta-analysis showed that systemic progress feedback of routinely obtained data of individual patients is beneficial in optimizing treatment of mental illness (25). This dissertation will focus on using ROM results for individuals in their treatment process. Progress feedback of ROM results is usually summarized in graphic displays by computer systems, and becomes part of routine practice. This methodology is efficient, cost-effective and generally well received by patients and clinicians (26). Similar recommendations were formulated in a report from the Trimbos Institute for the Dutch ministry of health, welfare and sport, which described the combination of ROM data and CDAs as an opportunity for improving treatment in Dutch mental healthcare (27). One example of a well implemented Dutch ROM program is the PHarmacotherapy Monitoring and OUtcome Study (PHAMOUS) screening protocol (28). PHAMOUS has been used since 2007 to assess symptomatic, physical and social wellbeing related care needs of people using

antipsychotic medication from multiple healthcare institutions in the Northern-Netherlands. Despite continuous improvements to the screening protocol, research indicates that PHAMOUS results are still not used to their full potential in mental healthcare (12,13). Connecting ROM data to decision support can be useful to identify needs and monitor progress in clinical practice and potentially improve guideline implementation.

Guideline implementation in mental healthcare: a tenuous endeavor

Generating scientific evidence, synthesizing research and developing guidelines is an advanced and well-organized process. In contrast, the subsequent process of guideline dissemination into regular clinical practice is far less developed. Guidelines provide a framework for best available evidence and are an invaluable source for clinical decisions in routine care (29). There are currently over 50 different guideline and care standards available in Dutch mental healthcare (<https://www.ggzstandaarden.nl/>), each covering hundreds of pages. This makes it increasingly difficult for clinicians to keep up with updates in available evidence. To reduce the risks that published guidelines become dated, digital living guidelines are continually updated by mental healthcare experts. They can increase accessibility and improve the dissemination of the latest scientific findings for clinicians in the field (30). Maintaining such systems for successful guideline implementation requires a substantial investment from different stakeholders (31). For example, a one-year targeted intervention to increase evidence-based practice in Dutch psychosis care lead to significant improvements, but still most patients did not receive evidence-based care in accordance with the national guidelines (32). In addition to the difficulties of implementation, guidelines are also challenged due to the inherent contradiction between personalized medicine and evidence-based practice. This contradiction is part of the scientific debate between the nomothetic and idiographic approaches (33). Results based on group level derived from clinical trials, often with strict inclusion criteria and conducted in specific clinical settings, may not always translate to the needs of individual patients in daily clinical practice. Moreover, evidence-based practice could be at odds with clinical expertise or experience from patient experts. Nevertheless, there is growing evidence that guideline adherence in specialized mental healthcare can improve clinicians

performance and patient outcomes (34,35), but the effects in most studies are modest and the knowledge about how to effectively implement these guidelines is inconclusive (36). A recent systematic review identified 35 studies describing CDAs used for successful implementation of guidelines in regular clinical practice in different healthcare settings (37). However, only two studies were conducted in a mental healthcare setting making it difficult to draw firm conclusions about their efficacy in this niche.

Connecting the dots: Treatment E-AssisT

Three challenges in mental healthcare have been outlined so far: improving clinical and shared decision-making, integrating ROM results in routine care, and implementing guidelines. CDAs have demonstrated their efficacy in improving aspects of all three of these challenges for routine clinical practice in several different medical disciplines. It remains to be seen whether CDAs can also contribute to these challenges in mental healthcare settings and, more specifically, in psychosis care. To connect these challenges, Lentis Psychiatric Institute collaborated with several mental healthcare institutions in the Northern-Netherlands, to create a computerized clinical decision aid named Treatment E-AssisT (TREAT). TREAT makes use of PHAMOUS data to assess care needs from patients with a psychotic disorder and combines these needs with information from guidelines and standards of care, to make personalized treatment recommendations for individual patients. These care needs and treatment recommendations are graphically displayed in the electronic patient file and can be used during treatment plan consultations to make shared decisions about the course of treatment.

Aim and outline of this dissertation

This dissertation focusses on the real-world implementation of a computerized clinical decision aid (TREAT) in psychosis care. **Part I** describes the background and development of TREAT in three chapters. In **Chapter 2**, the complexity which can arise when treating people with a psychotic illness is illustrated with a case. The added value of routine outcome monitoring and guidelines in psychosis care are discussed as well as some of the caveats when translating these to daily clinical practice with a CDA. **Chapter 3** describes the development and first evaluation

of the TREAT application. The findings from a pilot study are reported, in which TREAT was tested in daily clinical practice. The aim of this pilot was to investigate the feasibility of TREAT in a larger multicenter trial by evaluating clinicians' first experiences. The algorithms of TREAT identify psychiatric, physical and social wellbeing related care needs. In **Chapter 4**, we apply this logic to investigate patients' care needs in more detail in a longitudinal analysis with ROM data from the PHAMOUS screening. Appropriate care allocation for existing care needs is considered by some as the greatest academic challenge of modern-day mental healthcare (38). To gain a better understanding of this matter, care consumption data from the Diagnostic Related Groups (DRGs) was used to analyze the relations between care needs on several domains, care consumption and evidence-based pharmacotherapy.

Part II of this dissertation comprises three chapters in which the effects of TREAT in daily clinical practice are investigated. Previous research has shown that after the experimental evaluation period, less than half of all CDAs are still actively used by patients and clinicians (9). For successful implementation, it is pivotal to understand how these tools are used and appreciated by clinicians (and patients) in order to improve them for future use. **Chapter 5** describes a qualitative analysis of the experiences of clinicians which used TREAT in their clinical encounters. The aim of this study was to assess the ways in which clinicians used and evaluated TREAT and to collect information to improve the application for future use. **Chapter 6** reports the results from a clinical trial which investigated the effects of TREAT on the shared decision-making process as experienced by people with a psychotic illness. **Chapter 7** reports the results from the same clinical trial investigating the effects of TREAT on clinical decision making from a clinicians' point of view.

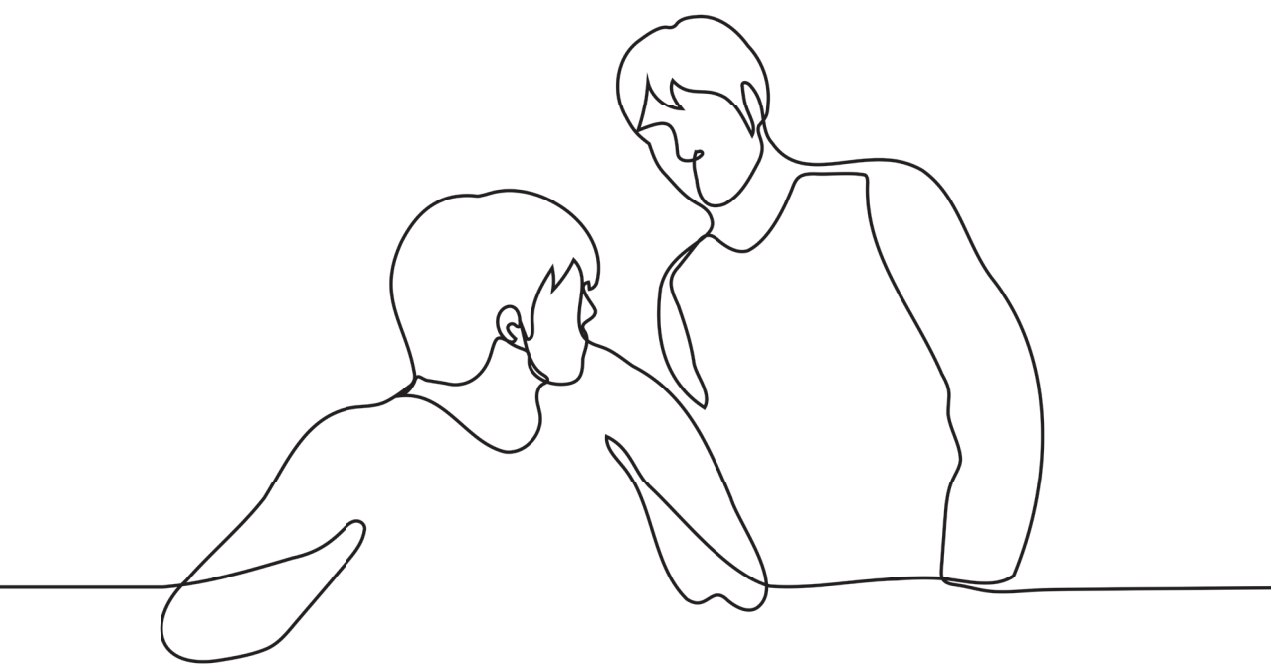
In **Chapter 8** the main findings of this dissertation are summarized and discussed. Additionally, a reflection on these findings provides recommendations on the future development and implementation of decisional support in mental healthcare.

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Chapter 2

Decision aid in the treatment of psychotic disorders: the development of Treatment E-Assist

Lukas O. Roebroek, Jojanneke Bruins, Rikus Knegtering, Richard Bruggeman, Philippe
A.E.G. Delespaul, Stynke Castelein

Tijdschrift voor Psychiatrie, volume 61, 2019

In this article we describe the development of a novel decision aid in Dutch mental healthcare: TReatment E-AssisT (TREAT), aimed at optimizing the treatment of people with a psychotic illness. We will first illustrate one possible use case through a brief case study.

Case Study

Patient A, a 33 year old single woman diagnosed with schizophrenia and an obsessive-compulsive disorder, was visited multiple times per year by her case manager. During these visits the patient appeared to be in a stable mood, expressed that she felt well and saw no need for any care, other than the question whether she could discontinue her medication. The previous year's her antipsychotics had been switched to 15mg of olanzapine, which had severely reduced the hallucinations she had previously experienced. Her doctor noted that her situation appeared stable, and thus advised against quitting her medication.

A yearly comprehensive routine outcome monitoring (ROM) screening revealed that she was doing less well than initially assumed. She reported almost no daytime activities and she was rated on the structured *Positive and Negative Syndrome Scale (PANSS)* as demonstrating negative symptoms. Furthermore, she was experiencing side-effects from her medication related to her sexual functioning while also putting on weight since switching to olanzapine. Laboratory research showed elevated fasting glucose levels of 6.8 mmol/l (norm 5.5 mmol/l) and triglyceride levels of 3.25 mmol/l. On a quality-of-life instrument she indicated being lonely and missing a significant other which she felt was related to the side-effects of her medication. These findings raised the idea that perhaps her request to quit medication was an implicit request for help that had gone unnoticed.

PHAMOUS

This case illustrates a common problem for people with a severe mental illness. Issues that are currently present may not be expressed, while at the same time other latent care needs could also exist. In order to identify these care needs a quality system with yearly screening for people with a severe mental illness was introduced ten years ago in the Northern-Netherlands. This system is called the PHArmacotherapy Monitoring and OUTcome Study also known as PHAMOUS (1).

This ROM screening has been extended and improved over the years. Currently, PHAMOUS has been implemented in multiple mental healthcare institutions in four (out of twelve) Dutch provinces. Using a systematic approach, PHAMOUS consists of a test battery assessing the mental and physical health, as well as the psychosocial wellbeing of persons using antipsychotic medication. The results of these yearly screenings are used by clinicians to discuss with patients how they are doing and find out which care needs exist, after which treatment plans are drafted or adjusted. This requires sufficient knowledge of evidence from guidelines and standards of care. Even highly knowledgeable clinicians indicate that they sometime struggle to find optimal treatment for people experiencing complex comorbid conditions.

Decision support for patients and clinicians

Despite the existence of evidence-based guidelines there are still many forms of treatment being offered for which the effectiveness has not yet been established by scientific research (<http://clinicalevidence.bmj.com/x/set/static/cms/efficacy-categorisations.html>). It can be difficult for clinicians to keep track of all the available information and for patients it can be even more challenging to acquire the information required to make informed decisions. This has caused an increased interest in so-called clinical decision aids, which can be used to support clinical decision-making and can improve the exchange of information before medical decision are made (2). In recent years, the use of these tools has increased in various medical disciplines such as oncology, cardiology and orthopedics. A recently published review analyzed more than 100 studies on clinical decision aids in different medical fields (3), and found that patients felt better informed about and more engaged in treatment decisions when a clinical decision aid was used, in comparison to treatment as usual. Perhaps more importantly, this resulted in patients reporting that the resulting treatment decisions were more in alignment with their personal preferences.

Customized guidelines?

The apparent contradiction between personalized medicine and evidence-based practice has been a source of debate. Can results from randomized controlled

trials and meta-analyses be generalized to situations in which patients choose to deviate from guidelines? Has personalized medicine resulted in the increase of interventions which lack evidence to support their effectiveness? Is scientific evidence based on group averages useful for individual care allocation? A recent meta-analysis (4) by Girlanda et al. showed that guideline concordant care for people with a severe mental illness can improve their clinical condition. Patients were also more satisfied with received care and had a smaller chance of rehospitalization. International research conducted in 20 different countries showed that two years of optimal evidence-based treatment resulted in greater symptomatic and psychosocial improvements compared to regular care for people with psychotic illness (5). The authors suggest that active strategies, such as decision aids, are needed to disseminate scientific evidence into daily clinical practice. In line with the popular value-based healthcare model (6), which emphasizes the importance of health outcomes which patients experience as meaningful, TREAT attempts to present treatment options in the treatment process once they become relevant for a specific patient. This may lead to shared decisions about which advice to use for a personalized treatment plan.

The first decision aids in mental healthcare

Are decision aids also making their introduction in the field of psychiatry? A demand for high quality clinical decision aids in mental healthcare is currently being voiced (7). Available literature about decision support in mental healthcare is scant. A cluster randomized study in the US showed lower rehospitalization rates for people with schizophrenia which were treated with a decision aid (8). These findings were replicated by a non-randomized German study which also demonstrated a reduction in clinical symptoms when a decision aid was used (9). A disadvantage of decision aids was the time investment for clinicians, for example because they had to collect all the patient's data themselves. Therefore, an efficient approach is needed as was documented in report from the Trimbos Institute for the Dutch ministry of health, welfare and sport. In this report it was recommended to combine routine outcome monitoring to decision aids in order to improve the treatment process in Dutch mental healthcare (10). Researchers and clinicians in the Northern-Netherlands with different background (psychiatrists, psychologists and nurse-practitioners) have worked closely together these past years to follow

up on these recommendations and create the user-friendly system that has been suggested. This resulted in the computer application TReatment E-AssisT (TREAT) (11). TREAT is accessible through an electronic patient record and identifies and displays relevant care needs for individual patients based on a routine outcome monitoring screening (PHAMOUS). The algorithms of TREAT combine the results of the PHAMOUS screening to multidisciplinary guidelines and standards of care (12). This way TREAT provides evidence-based personalized treatment advice for people with a psychotic illness during treatment plan consultations.

First evaluation of TREAT

Six clinicians (three psychiatrists, two nurse-practitioners and a physician) worked with TREAT during a pilot study. They experienced TREAT as user-friendly and indicated that they would like to continue working with the application once it becomes available. TREAT seemed to improve the integration of ROM results into daily clinical practice and provided treatment recommendations which clinicians had not considered or were unaware of. The recommendations were sometimes perceived as repetitive, or suggesting treatments which had already been tried before. We have to keep in mind that not all users have the same knowledge base. Medication recommendations or indications of abnormal blood values might be regular practice for a psychiatrist but not for a psychologist or nurse-practitioner. That is the reason why all clinicians were interviewed after the pilot study. All constructive criticism and point of improvements were used for the future development of TREAT. Two important improvements were the way in which TREAT deals with incomplete questionnaires as well as the integration of the newly released care standard for psychosis (13).

Bridging the gap

With TREAT we are hoping to bridge the gap between identifying care needs on all domains based on the PHAMOUS screening and the actual treatment of these specific needs. Various studies have shown that PHAMOUS is capable of timely signaling issues, yet adequate treatment was sometimes lacking. More specifically issues regarding positive and negative symptoms, hypertension and dyslipidemia (14-16). Implementing a ROM screening is not enough when striving for care

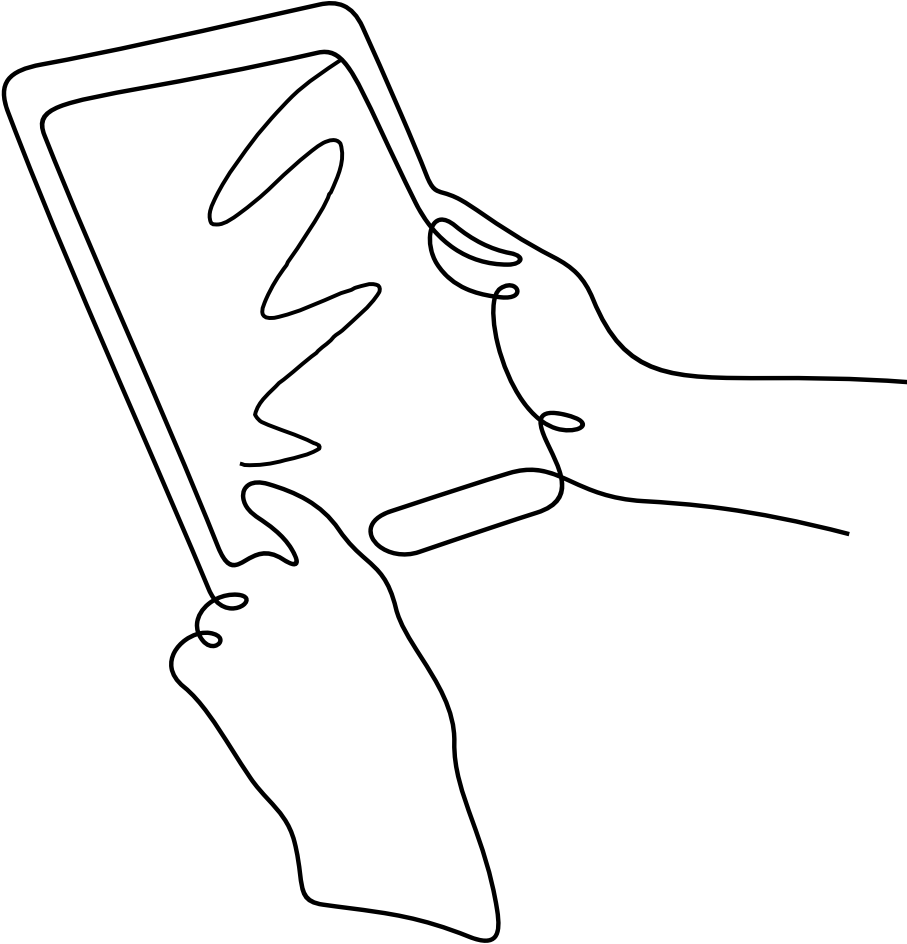
innovation. TREAT summarizes and graphically represent existing care needs of patients. Next, the algorithms select the relevant treatment options from multiple guidelines and standards of care, also taking into account the nature and severity of the needs. For the patient mentioned in the introduction, TREAT advised to switch to aripiprazole because of her complaints about being overweight and her sexual function disorder, a referral to her general practitioner for her abnormal blood values, and contact with peer groups to break her social isolation. This illustrates the way in which TREAT can contribute to the need for high quality clinical decision aids in mental healthcare. We are currently examining the effects of this tool in a multicenter study .

Conclusion

A clinical decision aid such as TREAT combines needs experienced by patients, as identified by the PHAMOUS screening, with information from guidelines and care standards. These needs and corresponding treatment recommendations are instantly made available to both the patient and their clinician. In this way TREAT might contribute to shared decision-making. In an attempt to improve care we also hope to stop under-treatment. The current trial will attempt to explore the possibilities of decision support in psychosis care.

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Chapter 3

The development and evaluation of a computerized decision aid for the treatment of psychotic disorders

Magda Tasma*, Lukas O. Roebroek*, Edith J. Liemburg, Rikus Knegtering, Philippe
A.E.G. Delespaul, Albert Boonstra, Marte Swart, Stynke Castelein

**Shared first author*

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ABSTRACT

Background: Routinely monitoring of symptoms and medical needs can improve the diagnostics and treatment of medical problems, including psychiatric. However, several studies show that few clinicians use Routine Outcome Monitoring (ROM) in their daily work. We describe the development and first evaluation of a ROM based computerized clinical decision aid, Treatment-E-Assist (TREAT) for the treatment of psychotic disorders. The goal is to generate personalized treatment recommendations, based on international guidelines combined with outcomes of mental and physical health acquired through ROM. We present a pilot study aimed to assess the feasibility of this computerized clinical decision aid in daily clinical practice by evaluating clinicians' experiences with the system.

Methods: Clinical decision algorithms were developed based on international schizophrenia treatment guidelines and the input of multidisciplinary expert panels from multiple psychiatric institutes. Yearly obtained diagnostic (ROM) information of patients was presented to treating clinicians combined with treatment suggestions generated by the algorithms of TREAT. In this pilot study six clinicians and 16 patients of Lentis Psychiatric Institute used the application. Clinicians were interviewed and asked to fill out self-report questionnaires evaluating their opinions about ROM and the effectiveness of TREAT.

Results: Six clinicians and 16 patients with psychotic disorders participated in the pilot study. The clinicians were psychiatrists, physicians and nurse-practitioners which all worked at least eight years in mental health care of which at least three years treating patients with psychotic illnesses. All Clinicians found TREAT easy to use and would like to continue using the application. They reported that TREAT offered support in using diagnostic ROM information when drafting the treatment plans, by creating more awareness of current treatment options.

Conclusion: This article presents a pilot study on the implementation of a computerized clinical decision aid linking routine outcome monitoring to clinical guidelines in order to generate personalized treatment advice. TREAT was found to be feasible for daily clinical practice and effective based on this first evaluation by clinicians. However, adjustments have to be made to the system and algorithms of the application. The ultimate goal is to provide appropriate evidence based care for patients with severe mental illnesses.

BACKGROUND

Treatment of psychotic disorders

Almost 1 % of the population in the western world will eventually fulfil the criteria of schizophrenia or a related severe mental illness (1). Core symptoms of many people suffering from psychotic disorders are hallucinations, delusions, incoherent thoughts, memory problems, loss of initiative, flat affect, poverty of speech and social withdrawal (2). Moreover, patients frequently experience problems with psychosocial functioning, such as a lack of daytime activities, social contacts, intimate relationships and a reduced quality of life (3,4). They often have poor physical health and experience medication side effects that contribute to an early onset of cardiovascular diseases. Different studies have shown a reduced life expectancy ranging from 10 up to 28 years (5,6). Some patients manage to recover both in terms of their symptoms, as well as in reaching personal and social goals. However the majority only partially recovers, with recurrence of symptoms and enduring personal and social problems often for the rest of their life. Especially patients with the most severe symptoms (fulfilling criteria for schizophrenia or schizoaffective disorders) often need lifetime medical, psychiatric and social care. Recommended treatment options are described in national treatment guidelines; in the Netherlands the Multidisciplinary Guideline for Schizophrenia is used (which is largely in line with the NICE guideline) (7). The Optimal Treatment Project revealed that two years of optimal, evidence-based treatment led towards a clear trend in recovery from clinical impairment and social disability of patients with psychotic disorders (8). Despite increasing evidence that pharmacological and psychosocial interventions are effective in improving clinical symptoms and patients' functioning, the availability of treatment interventions and integration in psychiatric care is often suboptimal (9). Also, many patients with psychotic disorders find it difficult to express their needs, show a decreased awareness of their symptoms and only partially understand the different possible treatment options. Therefore, psychological, medical and social problems often go undetected or untreated (10). There is a challenge to monitor symptoms and unmet care needs of these patients in order to offer optimal care, especially in realizing their varying needs in different domains for many years.

Routine outcome monitoring

Routine outcome monitoring (ROM) is one such way to monitor symptoms and care needs. ROM can be described as the use of standardized instruments to systematically and repeatedly measure different aspects of patients' symptoms, health, social functioning and wellbeing in order to improve their treatment (11,12). For patients with schizophrenia and related mental health problems, regular participation in ROM contributes to systematic evaluation of their varying needs in (mental) health care over many years. This could offer these patients relevant treatment options adjusted to actual needs. However, only few clinicians use ROM data in their day-to-day work (13,14). In the Northern Netherlands, an extensive ROM screening called the Pharmacotherapy Monitoring and Outcome Survey (PHAMOUS), consisting of a large array of instruments (15), has been implemented since 2007. Its main target is to identify needs of care in psychiatric, medical and social domains in order to optimize the treatment of patients with psychotic disorders. The data obtained also allows for scientific research. Although it has been shown that PHAMOUS successfully helps to identify unmet needs, it is still not optimally used in clinical decision making and in offering recommended evidence-based treatment options to people with psychotic disorders (16-18).

Treatment E-assist

There is often not just a single best option when making treatment decisions in healthcare. Different treatment options may have varying risks and benefits, making it challenging to offer the optimal option when decisions are sensitive to personal preference. Clinical decision aids (CDAs) are evidence-based tools to support decision making in healthcare and have been gaining popularity in various medical disciplines (19). A recent meta-analysis shows CDAs improve patients' knowledge about available treatment options, facilitate accurate risk perception and increase their active involvement in the decision making process (20). While knowledge about effective mental health care keeps growing, translation to daily clinical practice is lagging (21,22). CDAs can serve as a guideline implementation strategy by transferring evidence-based knowledge to day-to-day patient care. Despite the potential benefits of CDAs, their use in mental healthcare is very limited. In one study, a computerized CDA linking patient specific data to guidelines led to a decrease of symptoms and lowered re-hospitalization rates among people

with psychotic disorders (23). However, all diagnostic measurements for this CDA had to be collected by clinicians themselves, making the process time consuming. In the current study we describe Treatment E-Assist (TREAT). This is a recently developed computerized CDA that combines diagnostic patient data, collected using PHAMOUS, with guidelines. TREAT facilitates the use of PHAMOUS in daily clinical practice by summarizing patients' unmet needs. As a second step, evidence-based treatment recommendations based on the Multidisciplinary Guideline for Schizophrenia are generated to assist the clinician and patient to make shared decisions about these unmet needs.

Research aim

This article describes the development of TREAT and the results of the pilot study, evaluating TREAT, as a computerized CDA designed for the treatment of patients with psychotic disorders. The pilot study tests the feasibility of TREAT in daily clinical practice by evaluating clinicians' experiences when working with the application.

METHODS

Substantive design

The algorithms of TREAT are based on PHAMOUS data and the Multidisciplinary Guideline for Schizophrenia (7). The algorithms were designed in collaboration with two multidisciplinary expert panels, both consisting of 7 members representing different institutions. These panels included researchers, psychiatrists, psychologists and nurse-practitioners, all experienced in working with PHAMOUS. The first panel focused on somatic problems and pharmacotherapy and the second panel focused on psychosocial interventions. Participants from the expert panels did not participate in the pilot study described hereafter.

The first session of the expert panels was an introduction of the project and a brainstorm to collect first ideas and thoughts. Next, researchers proposed possible problematic domains in care for people with a psychotic disorder: positive symptoms, negative symptoms, cognitive symptoms, psychosocial problems, and somatic problems. Each domain was further divided into subcategories. The

researchers selected matching items from the PHAMOUS instruments for each subcategory and proposed cut-off scores. TREAT displays these subcategories as problematic when patient measures on the matching instruments exceed the cut-off scores. The draft proposal was then discussed with the panels, until consensus was reached. Cut-off scores were based on expert opinions when explicit guidelines were lacking. Instead of the Multidisciplinary Guideline for Schizophrenia (7), the pharmacotherapy panel decided to use a more detailed guideline for the treatment of cardiovascular risk factors based on the input of somatic doctors working in psychiatry (of Mental Health Care Center Drenthe, The Netherlands). This guideline (Guideline for Cardiovascular Risk Management Drenthe) offers cut-off scores and treatment recommendations on cardiovascular risk factors for patients who have been using antipsychotic medication for a long period of time. Finally, the researchers proposed treatment recommendations to both panels for each care domain, based on the Multidisciplinary Guideline for Schizophrenia (7). Treatment recommendations were complemented where necessary and discussed until consensus was reached. The final TREAT algorithms were discussed with two guideline experts (HK and SC) to assess whether the Multidisciplinary Guideline for Schizophrenia (7), had been properly followed. Figure 1 depicts a schematic of TREAT.

Figure 1. Schematic of TREAT



Program design

PHAMOUS and TREAT were both developed by a company (RoQua) that specializes in privacy protecting ROM systems that are accessed via the electronic patient record. TREAT has been built as an addition to the PHAMOUS system and

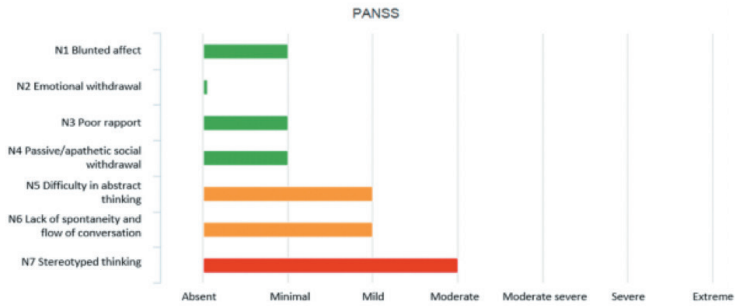
generates an interactive (Dutch) report for each individual patient. The first part of the report displays a summary of the PHAMOUS results. It contains a graph depicting symptom dimensions, treatment effects, patient satisfaction and unmet needs in different areas of life, such as mental health, physical health and antipsychotic medication. It also depicts general information about the patient, for instance the types of treatment the patient has received during the previous year. Finally, an overview is depicted of all care domains that are measured by PHAMOUS highlighting (in blue) which areas might (still) be problematic for a patient as depicted in figure 1. When a clinician selects a care domain, the relevant instruments, items, scores and treatment recommendations are displayed. In the graphs, the color of a bar indicates the severity of the problem (green = no problem, orange = potential problem and red = problem). On each page that depicts a care domain, one can click on the “back to overview” button to move back to the summary page. Clinicians can navigate through the TREAT report to assess all relevant PHAMOUS results and treatment recommendations of a patient as depicted in figures 2 and 3.

Figure 2. First screenshot of TREAT

Negative symptoms

[Back to overview](#)

Negative symptoms are (still) present



Treatment advice

Psychosocial treatments

Cognitive behavioural therapy (CBT) is recommended for negative symptoms. Individual therapy is preferred, with a minimum of sixteen sessions being offered per protocol. It has been shown that CBT compared to regular care leads to a reduction of negative symptoms from 12 till 24 months after treatment ([level 1](#)).

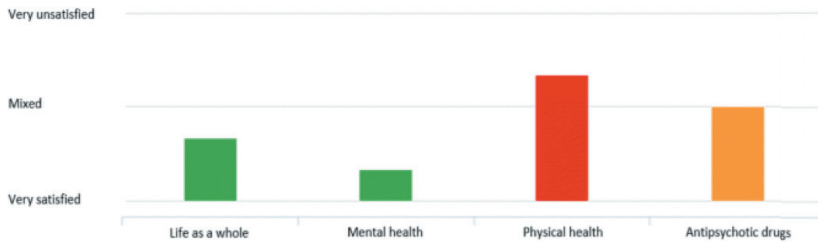
Consider participation in **peer support groups** in case of negative symptoms. It is likely that companion groups have a positive effect on negative symptoms ([level 2](#)).

Consider **music therapy** in case of severe negative symptoms. It is likely that music therapy compared to regular care leads to a reduction of negative symptoms after treatment ([level 2](#)).

Consider **psychomotor therapy (PMT)** in case of severe negative symptoms, such as delayed psychometry. There is evidence that psychomotor therapy compared to counselling leads to a reduction of negative symptoms up to four months after treatment ([level 3](#)).

Please note: Besides offering interventions for negative symptoms, promoting activation is recommended. For example, stimulate the patient to join a club, do volunteer work or provide (more) meaningfulness.

Patient satisfaction



Areas of interest

Symptoms	Physical	Psychosocial
<ul style="list-style-type: none"> Positive symptoms Negative symptoms Depressive symptoms Compulsive symptoms Substance abuse Agitation / aggression Anxiety Self-harm 	<ul style="list-style-type: none"> Hypertension (Pre)diabetes type II Hyperlipidaemia Weight Smoking Movement disorder Sexual dysfunction Hyperprolactinaemia Anticholinergic side effects 	<ul style="list-style-type: none"> Social relationships Intimate relationships Sexuality Living conditions Daytime activities Family Personal safety

Figure 3. Second screenshot of TREAT

Weight
[Back to overview](#)
 There is overweight

Measure	Value	Norm	Norm exceeded
BMI	28 kg/m ²	<25 kg/m ²	Yes
Waist circumference	110 cm	<102 cm	Yes

SRA-34

3. Have I gained weight
 32. Has my appetite increased

No Yes, moderately Yes, strongly

Treatment advice overweight
 Provide lifestyle advice: education about exercise and a healthy diet.
 Consider **psychomotor therapy (PMT)** or **exercise activation**. It is likely that diet combined with exercise will lead to weight reduction and lowering of the BMI (level 2).
 Consider reference to a dietician, fitness or a psychologist. Also check the "Guideline Obesity" from the CBO.²

Social relations
[Back to overview](#)
 There is dissatisfaction/ there are problems with social relations

MANS

12. How satisfied are you with your social relations?

Very satisfied Satisfied A little satisfied Mixed A little dissatisfied Dissatisfied Very dissatisfied

HoNOS
 Missing answers are depicted in grey

9. Problems with relationships

No problem Minor problem Mild problem Moderately severe problem Severe to extreme problem

Treatment advice
 Consider participation in **peer support groups** when dissatisfied with social relationships. It is likely that companion groups have a positive effect on the size of the social network and received social support (level 2).
 Please note: It is recommended to stimulate the patient to seek out more social contact, for example by joining a club or by participating in voluntary work.³

Pilot study

Participants

Six clinicians and sixteen patients of two (outpatient) Functional Assertive Community Treatment (FACT) teams of Lentis Psychiatric Institute participated in the pilot study. The clinicians were three psychiatrists, two nurse-practitioners and one physician. Patients were eligible for the study when they had a DSM IV diagnosis on the psychosis spectrum, or a personality or mood disorder with psychotic features. All patients filled out an informed consent form. The procedures were in accordance with the declaration of Helsinki as confirmed by the Medical Ethics Committee of the University Medical Center Groningen.

Procedure

Before the clinicians started using TREAT, they were asked to fill out a questionnaire that assessed their opinions about PHAMOUS. Next, each clinician used TREAT before and/or during the discussion of the PHAMOUS results with a patient. The first three patients with psychotic disorders scheduled to have an appointment with their clinician to discuss their yearly ROM results, were asked to participate in the study. One of the six clinicians only participated with one patient due to planning issues during the time of this pilot study and patients declining to participate. The nurse who performed the PHAMOUS screening was instructed to create the individual TREAT report. Both the nurses and the clinicians received instructions about TREAT from a researcher (MT). During these hour long treatment sessions, PHAMOUS results are discussed and treatment plans are drafted or adjusted. Afterwards, clinicians and patients filled out a questionnaire about the clinical decision making process during the sessions. This included questions about the topics that were discussed and the treatment options that were considered. At the end of the pilot study, clinicians filled out a questionnaire and participated in a brief open interview that both assessed their experiences with TREAT.

Measures

Assessments were made with two self-developed, theory-based Dutch questionnaires. The first one was the 'ROM State-of-Mind' consisting of 24 items, with the first 22 items assessing participants' acceptance of PHAMOUS on a Likert scale from 1 (completely disagree) to 5 (completely agree). Item 23 assessed overall appreciation of PHAMOUS on a scale from 1 (very poorly) to 10 (excellent) and item 24 was an open question about suggestions and comments regarding PHAMOUS. Items constituted seven subscales, of which five had a high internal consistency (Cronbach's Alpha $\geq .7$) and two a low internal consistency (Cronbach's Alpha $< .4$) (18).

Secondly, participants filled out the 'TREAT State-of-Mind' consisting of 27 items assessing statements about TREAT, each rated on a Likert scale from 1 (completely disagree) to 5 (completely agree). The items constituted eight subscales, measuring usage behaviour, support, power, issue-impact, emotion, ease of use, usefulness, and facilitating conditions. The following two items assessed the acceptance of TREAT in general and the integration of both TREAT and PHAMOUS. Both items were rated on a scale from 1 (very poorly) to 10 (excellent). The next item was an open question to collect ideas, comments or suggestions about TREAT.

The questionnaire also registered the amount of times clinicians consulted TREAT and for how long they had used TREAT on average per consult. The remaining six items assessed clinicians' characteristics: profession, department, gender, age, and number of years working in mental health care and psychosis care. We used the Clinical Decision Making in Routine Care (CDRC) questionnaire (24), to assess the treatment sessions. This questionnaire was translated in to Dutch and expanded with specific categories, largely representing the problems that are assessed with TREAT (see Additional file 1). The CDRC has a staff and patient version, consisting of 22 and 21 items each. The original authors, CEDAR study group, provided permission to use the questionnaire.'

RESULTS

Clinicians' experiences with ROM and TREAT

All clinicians had worked with PHAMOUS for 7 years on average (ranging from 3 years to 9 years). They were generally positive about PHAMOUS, grading it with an average of 7 (SD 0.89) on a scale from 1 (poor) to 10 (excellent). They have positive feelings towards PHAMOUS (subscale 'emotion'), see it as a useful addition to their job (subscale 'usefulness'), but don't find it very easy to use (subscale 'ease of use'). Results are depicted in Table 1. Clinicians were also positive about TREAT with an average rating of 7.5 (SD 0.84) and the integration of TREAT and PHAMOUS with an average rating of 7.3 (SD 1.37) on a scale from 1 (poor) to 10 (excellent). Most clinicians had used TREAT at least three times during the pilot study, with the exception of one clinician who only worked with TREAT a single time. The time TREAT was used differed per user: 5 to 15 min (1 psychiatrist), 15 to 30 min (1 nurse-practitioner and 1 physician) and more than 30 min per session (2 psychiatrist and 1 nurse-practitioner). Most clinicians find TREAT useful and expect it will help them improve their work. They state that it helps to interpret the (diagnostical) PHAMOUS results and offers support in drafting the treatment plan. It also enhances awareness of the existing treatment options (subscale 'usefulness'). TREAT fits with good clinical care, clinicians are proud of its development (subscale 'emotion') and expect to use TREAT in the future (subscale 'usage behaviour'). TREAT is thought to be easy to use and requires little mental effort. Opinions about the lay-out of TREAT are mixed (subscale 'ease of use'), for example some clinicians preferred the graphs displaying data vertically whilst others preferred it horizontally. Most clinicians state that they have enough time to use TREAT in daily clinical practice and that it helps them to work more efficiently (subscale 'facilitating conditions'). They do not think TREAT will have impact on their professional autonomy (subscale 'power'), on their job or on patient care in general (subscale 'issue-impact'). Results are depicted in Table 2. Some clinicians preferred to use TREAT on the computer while others preferred to print the information. The topics that were mentioned in the open interview are depicted in Table 3.

Table 1 Scores on the ROM State-of-Mind questionnaire (clinicians n=6)

Subscale	Items	Mean Score (SD)
Acceptance	2. I use ROM-Phamous results in the treatment of my patients.	4.00 (0.63)
	22. I actively use the information offered by ROM-Phamous.	3.00 (0.63)
Support	1. I express my concerns about ROM.	3.00 (1.27)
	21. I tell people that it's good that ROM-Phamous exists.	3.50 (1.52)
Power	13. I experience ROM-Phamous as a form of behavioural control.	1.67 (0.52)
	18. Because of ROM-Phamous I have more control over my job.	2.83 (0.75)
Emotion	5. Use of ROM-Phamous fits with my professional values and beliefs.	4.00 (0.89)
	6. Use of ROM-Phamous fits with good clinical care.	4.67 (0.52)
	7. I am proud that ROM-Phamous is used in my institution.	3.67 (0.82)
	8. I am worried about the existence of ROM-Phamous.	2.17 (1.47)
Ease of use	3. ROM-Phamous results are easy to interpret.	3.00 (0.89)
	9. ROM-Phamous is easy to use.	2.83 (0.75)
Usefulness	10. Working with ROM-Phamous requires little (extra) mental effort.	2.67 (0.82)
	4. ROM-Phamous adds value to the treatment of my patients.	4.33 (0.52)
	11. Because of ROM-Phamous I am better able to perform my job.	3.67 (0.82)
	12. Because of ROM-Phamous I am better supported in my job.	4.17 (0.75)
	15. The instruments of the ROM-Phamous protocol provide me with enough valuable information about my patients.	3.83 (0.41)
	16. ROM-Phamous identifies care needs.	4.00 (0.63)
	17. Because of ROM-Phamous more thought goes into care modules.	3.50 (0.55)
	14. I have enough time to use ROM-Phamous in my daily work.	2.00 (0.63)
Facilitating conditions	19. Because of ROM-Phamous I am able to work more efficiently.	3.50 (0.55)
	20. Using ROM-Phamous costs extra time.	3.50 (0.84)

1 = completely disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = completely agree, - = no opinion

Table 2 Scores on the TREAT State-of-Mind questionnaire (clinicians n=6)

Subscale	Items	Mean Score (SD)
Usage behaviour	2. If it is up to me, I will start using TREAT as soon as possible.	4.17 (1.60)
	3. When TREAT becomes available I will actively use it.	4.83 (0.41)
Support	1. I express my concerns about TREAT.	3.00 (2.19)
	26. I will tell people it is good TREAT has been developed.	3.33 (1.86)
Power	4. Because of TREAT I expect to have more influence on the way I do my job.	3.50 (0.55)
	5. Because of TREAT I expect to become more dependent on others.	1.83 (0.41)
	18. I experience TREAT as a form of behavioural control.	1.50 (0.84)
Issue-impact	6. My job will remain about the same with TREAT.	3.33 (1.21)
	7. I expect TREAT to have much influence on the way I do my job.	3.00 (0.89)
	8. I expect TREAT to have much influence on the way most clinicians of the psychosis department do their job.	3.17 (1.17)
	9. I expect TREAT to have much influence on patientcare in the psychosis department.	3.50 (1.52)
Emotion	10. Use of TREAT fits with my professional values and beliefs.	3.67 (0.82)
	11. Use of TREAT fits with providing good clinical care.	4.33 (0.52)
	12. I am proud of the fact that TREAT has been developed and is being investigated.	4.17 (0.98)
	13. I am worried about the introduction of TREAT.	2.00 (1.10)
Ease of use	14. TREAT is easy to use.	4.33 (0.82)
	15. Working with TREAT requires little (extra) mental effort.	4.33 (0.52)
	20. The lay-out / arrangement of TREAT appeals to me.	3.17 (1.47)
Usefulness	16. I expect to be able to better perform my job, because of TREAT.	4.42 (0.66)
	17. I expect to receive more support in my job, because of TREAT.	3.67 (1.03)
	21. TREAT helps with the interpretation of the ROM-Phamous outcome.	4.33 (0.82)
	22. I expect TREAT to offer support in drafting the treatment plan.	4.17 (1.17)
	23. Because of TREAT I am more aware of the different treatment options that are available.	3.92 (0.67)
	27. Because of TREAT I am more aware of the purpose of ROM-Phamous.	2.67 (1.21)
Facilitating conditions	19. I expect to have enough time to use TREAT in my daily work.	4.00 (1.10)
	24. Because of TREAT I can work more efficiently.	4.08 (0.49)
	25. Using TREAT costs extra time.	2.33 (1.03)

1 = completely disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = completely agree, - = no opinion

Table 3 Topics mentioned in the brief open interview about TREAT (clinicians n=6)

Positive feedback	Negative feedback
TREAT improved the efficiency of the treatment session. ⁵	The treatment recommendations were sometimes repetitive, when patients had already received certain treatment options in the past. ^{1,3}
TREAT was a good reminder to talk about certain topics, which otherwise might be forgotten. ^{3,5}	The specific diagnosis of the patient was not mentioned in TREAT. ³
The visual feedback was experienced as pleasant. ³	The treatment recommendations did not add much, new information. It was however convenient to explicitly go through the different options. ⁴
The visualizations were especially useful for the patient and it led to more shared-decision making. ¹	The cut-off scores for the somatic parameters in TREAT were different than the cut-off scores the general practitioner uses. This is confusing. ²
Because of TREAT the discussion of the ROM results became a more explicit moment to make decisions. ¹	The print version of TREAT was too long. The graphs take up much space. ²
When the treatment guidelines change, TREAT needs to be updated. The maintenance of TREAT is important. ²	The information the ROM nurse added to the ROM results did not appear in TREAT. Because of this, important information was sometimes missing. ²
ROM-Phamous was confusing and TREAT has made this better and clearer. ⁶	It is a risk that clinicians will only follow TREAT and forget about other potential problems. ⁵
Certain treatment options in the recommendations were new and I would not have thought of these options without TREAT. An example was 'peer support groups'. ⁶	It would be helpful if TREAT could also lead to a template for a treatment plan. ⁵
The treatment session was more structured and I had the feeling we had discussed all the important issues, because of TREAT. ⁵	It would be nice to be able to compare ROM results of previous years with current results. ¹

Clinician identifier: 1, 2, 3, 4, 5 & 6

Feasibility of questionnaires

Both clinicians and patients completed the CDRC questionnaires. All clinicians filled out the staff version of the CDRC but some of the patients experienced difficulties with their version of the questionnaire. They remembered most of the topics discussed in the feedback sessions but some had trouble to be specific or to categorize the different topics or mention specific treatment options that were suggested.

DISCUSSION

A ROM inventory in 2011, for the Dutch ministry of health, welfare and sport, recommended combining ROM to CDAs to improve the treatment process within mental healthcare (25). Despite these recommendations such systems are currently unavailable. With TREAT, a computerized CDA has been developed linking ROM to treatment guidelines. In this way TREAT generates personalized treatment advice for the treatment of patients with psychotic disorders. The primary aim of this pilot study was to describe the development of TREAT and assess its feasibility for daily clinical practice.

Clinicians' evaluations

In general clinicians were positive about working with TREAT. Most of them found the system easy to use without requiring extra mental effort or time. This is important as usability and limited time investment are the two most important factors affecting successful implementation of CDAs (26). One clinician did prefer the printed TREAT report for the feedback sessions because this person felt that the computer could disturb communication with patients. However, concerns from a previous study that computer use would be distracting, decrease eye contact or depersonalize the interaction (27), were not replicated. All clinicians indicated they would like to continue working with TREAT as they found it fitting with good clinical practice. Some concerns were expressed about the recommendations being or becoming too familiar over time. Lack of novelty could potentially stop clinicians from working with the application. In contrast, some clinicians became more aware of guidelines and discovered new treatment options. There is growing evidence that treatment in accordance with guidelines within mental

healthcare, can positively affect patient care (8,28,29). One clinician suggested that the PHAMOUS results of previous years should be incorporated in order to evaluate changes over time. This exemplifies that the TREAT algorithms can be improved and tailored even more to individual patients. CDAs sometimes fail to take contextual information into account or have algorithms that insufficiently fit complex patient scenarios (30). When asking clinicians about their opinions regarding PHAMOUS, they indicated that the outcomes are not always easy to use for clinical decision making. This is in line with previous studies showing that the outcomes of PHAMOUS are not used to its full potential in daily clinical practice (17,18,31). TREAT simplifies the interpretation of these outcomes and facilitates a basis for more explicit decision making. Future research should focus on the effects of TREAT in the clinical decision making process. Lessons learned can improve the TREAT application, but may also help to develop other CDA's.

Future adjustments & research

Adequately informing patients about their health and available treatment options is the future of healthcare, in which CDAs should play a pivotal role. While CDAs are commonly used in medical fields such as oncology, orthopedics and cardiology, its use in mental healthcare is still very rare. With TREAT a high quality and easy to use CDA is now available in this field. Some adjustments will be made to the system based on the results of this pilot study. For instance the algorithms will be updated to ensure that TREAT reports can still be generated when part of the data is missing. PHAMOUS consists of multiple instruments so patients are not always able to complete all questionnaires. Furthermore, two printable versions of the TREAT report will be added, namely a summary and the complete report. These adjustments will enable a large follow-up study aiming to investigate the effects of TREAT on clinical decision making. Because there are hardly any validated methodologies available to assess the content of treatment sessions in mental healthcare, modified and translated versions of the CDRC questionnaires were tested. Clinicians were able to fill out their version. However, patients experienced difficulties in categorizing the different topics that were discussed during the treatment sessions. These difficulties probably reflect cognitive difficulties in line with their psychiatric problems. Therefore, we will use only the staff version of the CDRC questionnaire for future research. Clinicians reported that patients

appreciated the TREAT report and that it could improve shared decision-making. Previous research in somatic medicine supports the notion that CDAs are effective in improving shared decision-making (20). Recently there have been calls for widespread access to CDAs to improve the level of shared decision-making within mental healthcare (32). Patients prefer an active role in the decision-making process and are more likely to adhere to their treatment plans if they actively participated in the draft (33). The follow-up study is designed to assess whether CDA's, in this case TREAT, can indeed increase shared decision-making within a mental healthcare setting. So far research on computerized CDAs shows that they may improve disease management and diagnostics, however the effects on patients' functioning and final clinical outcome remains unclear (34). Assessing the effects of TREAT on patients' symptoms, physical health and psychosocial functioning, will be another important goal of the follow-up study. If a CDA like TREAT is beneficial in treatment of psychotic disorders, it might be worthwhile to develop similar systems for different patient groups.

Strengths and limitations

To the best of our knowledge, this study presents the first computerized CDA combining ROM and treatment guidelines in an electronic patient record within mental health care. TREAT was developed in close collaboration with healthcare professionals. This is a strength of TREAT, as sufficient knowledge of developers about the target group of CDAs is important for successful implementation (26). ROM is sometimes experienced as behavioral control by some users who feel obliged by political or financial motives (18). This was not replicated in previous or the current study (17,18), as all clinicians had positive opinions about PHAMOUS. A limitation of the current study is the small sample of only six clinicians from the same psychiatric institute. Although large enough to test the applicability of TREAT in daily clinical practice, a larger sample of clinicians from multiple centers are preferred when testing the effects of the application on the clinical decision making process and patient outcomes.

Conclusions

This pilot study describes the development and first evaluation of a computerized CDA (TREAT) linking ROM to clinical guidelines to generate personalized treatment recommendations in the treatment of psychotic disorders. The primary aim was to assess the feasibility of TREAT for daily clinical practice by evaluating clinicians' opinions when working with the system. In sum, clinicians found TREAT useful for daily clinical practice, easy to use, fitting with good clinical care and all of them would like to use the system in the future. TREAT was not felt to reduce clinicians' professional autonomy nor was it perceived as behavioral control. Clinicians expect TREAT to have a positive impact on their daily job but are unsure if it will improve patient outcomes, such as reduced symptoms and improved psychosocial wellbeing. The application will be adjusted and improved for a follow-up study based on the results from this pilot. The follow-up study will investigate the effects of TREAT on shared decision-making, the clinical decision-making process and patient outcomes.

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APPENDIX

Clinical decision making in daily care - Staff version

(Clinical Decision-making in Routine Care – Staff (CDRC-S))*

These questions are about the consult with your patient

1. When did the consult took place? (DD.MM.YYYY)

--	--	--	--	--	--	--	--	--	--

2. When did the ROM-Phamous screening took place? (DD.MM.YYYY)

--	--	--	--	--	--	--	--	--	--

3. When did the ROM-Phamous discussion took place? (DD.MM.YYYY)

--	--	--	--	--	--	--	--	--	--

4. How long did the consult take? (min.)

--	--

5. Did you use TREAT for this consult?

Yes

NO

6. If the consult was not completed in one session, please indicate when the second session took place.

--	--	--	--	--	--	--	--	--	--

(DD.MM.YYYY)

--	--

(min.)

7. Are you the primary clinician of this patient?

YES

NO

8. What is your occupation?

- Nurse-practitioner
- Psychiatrist
- Psychologist
- Physician
- Different _____

9. What were the topics about which you and your patient had to make a decision during the consult.

Please indicate which topics were discussed and whether or not a decision was made about the treatment. Please also indicate which decision was made or why no decision was made. Keep in mind that not changing the current situation is also a decision.

	<i>Not discussed</i>	<i>Discussed, no decision</i>	<i>Discussed, with decision</i>
Positive symptoms	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Dose increase antipsychotic <input type="checkbox"/> Change antipsychotic <input type="checkbox"/> Add medication to antipsychotic <input type="checkbox"/> rTMS <input type="checkbox"/> ECT <input type="checkbox"/> CBT <input type="checkbox"/> HIT <input type="checkbox"/> Psycho education <input type="checkbox"/> No changes <input type="checkbox"/> Different
Negative symptoms	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Dose increase antipsychotic <input type="checkbox"/> Change antipsychotic <input type="checkbox"/> Add medication to antipsychotic <input type="checkbox"/> rTMS <input type="checkbox"/> ECT <input type="checkbox"/> CBT <input type="checkbox"/> Peer support groups <input type="checkbox"/> Music therapy <input type="checkbox"/> Psychomotor therapy <input type="checkbox"/> Stimulate activation <input type="checkbox"/> No changes <input type="checkbox"/> Different
Depressive symptoms	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Specific treatment depression <input type="checkbox"/> Lower dose antipsychotic <input type="checkbox"/> Change antipsychotic <input type="checkbox"/> Add antidepressant to antipsychotic <input type="checkbox"/> No changes <input type="checkbox"/> Different

OCD	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Specific treatment for OCD <input type="checkbox"/> No changes <input type="checkbox"/> Different
Substance abuse	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Specific treatment substance abuse <input type="checkbox"/> Add clozapine <input type="checkbox"/> No changes <input type="checkbox"/> Different
Aggression	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Add Clozapine <input type="checkbox"/> Psychomotor therapy <input type="checkbox"/> No change <input type="checkbox"/> Different
		<i>Not discussed</i>	<i>Discussed, no decision</i>
Anxiety	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Specific treatment anxiety <input type="checkbox"/> Change dose antipsychotic <input type="checkbox"/> No change <input type="checkbox"/> Different
Social relationships	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Peer support groups <input type="checkbox"/> Stimulate activation <input type="checkbox"/> No change <input type="checkbox"/> Different
Intimate relationships	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Peer support groups <input type="checkbox"/> No change <input type="checkbox"/> Different
Relationship with family	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Use Triade map <input type="checkbox"/> No change <input type="checkbox"/> Different
Sexuality	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Lower dose antipsychotic <input type="checkbox"/> Change antipsychotic <input type="checkbox"/> Add medication <input type="checkbox"/> No change <input type="checkbox"/> Different

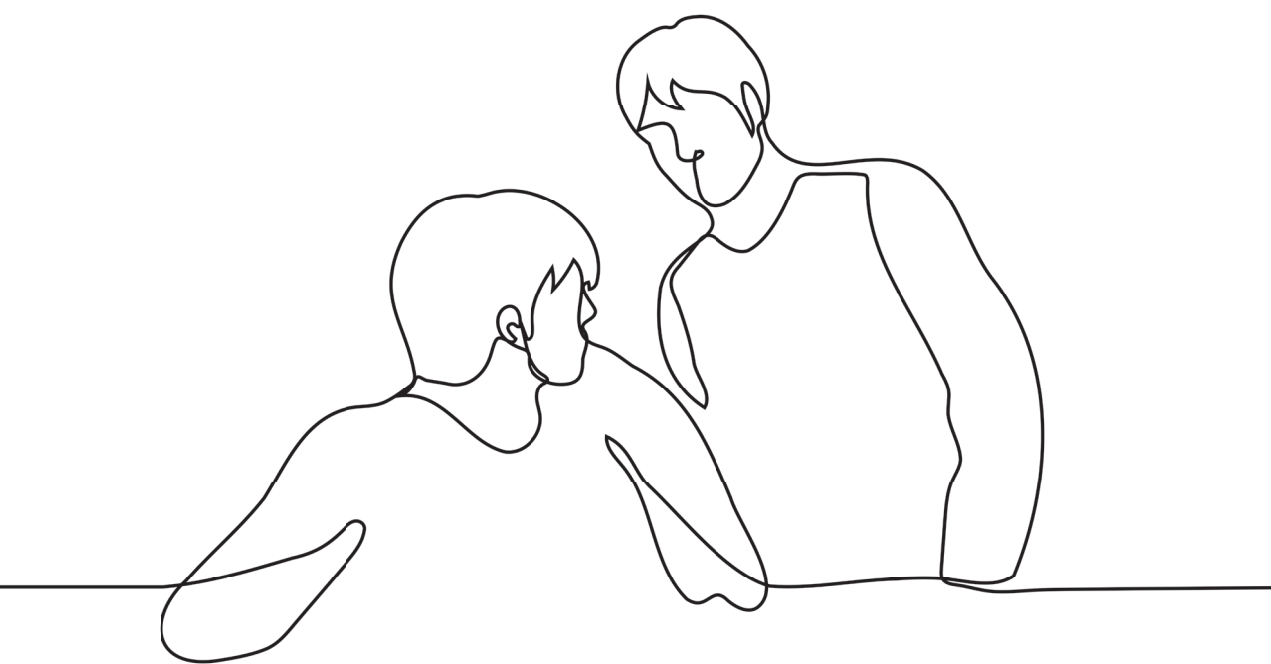
	<i>Not discussed</i>	<i>Discussed, no decision</i>	<i>Discussed, with decision</i>
Housing	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> No changes <input type="checkbox"/> Different
Daly activity	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> IRB <input type="checkbox"/> IPS <input type="checkbox"/> No changes <input type="checkbox"/> Different
Personal safety	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> No changes <input type="checkbox"/> Different
Hypertension	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Lifestyle advice <input type="checkbox"/> Reference to physician <input type="checkbox"/> No changes <input type="checkbox"/> Different
(Pre)diabetes II	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Lifestyle advice <input type="checkbox"/> Reference to physician <input type="checkbox"/> No changes <input type="checkbox"/> Different
	<i>Not discussed</i>	<i>Discussed, no decision</i>	<i>Discussed, with decision</i>
Dyslipidemia	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Lifestyle advice <input type="checkbox"/> Reference to physician <input type="checkbox"/> No changes <input type="checkbox"/> Different
Weight	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Lifestyle advice <input type="checkbox"/> Psychomotor therapy <input type="checkbox"/> Reference to dietitian or physician <input type="checkbox"/> No changes <input type="checkbox"/> Different

Smoking	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Stop smoking course <input type="checkbox"/> Reference to specialist <input type="checkbox"/> No changes <input type="checkbox"/> Different
Movement disorder	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Change antipsychotic <input type="checkbox"/> Different medication <input type="checkbox"/> No changes <input type="checkbox"/> Different
		<i>Not discussed</i>	<i>Discussed, no decision</i>
Heightened Prolactin levels	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Change dose antipsychotic <input type="checkbox"/> Quit antipsychotic <input type="checkbox"/> No changes <input type="checkbox"/> Different
Anti-cholinergic side-effects	<input type="checkbox"/>	<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Patient declines treatment <input type="checkbox"/> Different	<input type="checkbox"/> Lower dose antipsychotic <input type="checkbox"/> Change antipsychotic <input type="checkbox"/> Lifestyle advice <input type="checkbox"/> No changes <input type="checkbox"/> Different
Other discussed topics (please specify)		<input type="checkbox"/> Patient wants to re-evaluate treatment options <input type="checkbox"/> Different	<input type="checkbox"/> No changes <input type="checkbox"/> Different

Thank you for completing this questionnaire.

* Deze vragenlijst is gebaseerd op de CDRC vragenlijst van de CEDAR study group**. Wij hebben de lijst naar het Nederlands vertaald en aangevuld om hem passend te maken voor het TREAT-onderzoek.

** Konrad J, Loos S, Neumann P, Zentner N, Mayer B, Slade M, Jordan H, De Rosa C, Del Vecchio V, Égerházi A, Nagy M, Krogsgaard Bording M, Østermark Sørensen H, Kawohl W, Rössler W, Puschner B (2015) *Content and implementation of clinical decisions in the routine care of people with severe mental illness*, Journal of Mental Health, **24**, 15-19.



Chapter 4

Care needs and care consumption in psychosis: a four year longitudinal analysis of guideline concordant care

Lukas O. Roebroek, Jojanneke Bruins, David Roe, Philippe A.E.G. Delespaul, Agna Bartels-Velthuis, Richard Bruggeman, Frederike Jörg, Rikus Knegtering, Marieke Pijnenborg, Wim Veling, Steven de Jong, Albert Boonstra, Ellen Visser & Stynke Castelein

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ABSTRACT

Aims: People with psychotic disorders receive mental healthcare services mainly for their psychiatric care needs. However, patients often experience multiple physical or social wellbeing related care needs as well. This study aims to identify care needs, investigate their changes over time and examine their association with mental healthcare consumption and evidence-based pharmacotherapy.

Methods: This study combined annual obtained Routine Outcome Monitoring data (ROM) with care consumption data of people with a long-term psychotic illness receiving treatment in four Dutch mental healthcare institutes between 2012 and 2016. Existing treatment algorithms were used to determine psychiatric, physical and social wellbeing related care needs based on self-report questionnaires, semi-structured interviews and physical parameters. Care consumption was measured in hours of outpatient mental healthcare consumption per year. Generalized estimating equations models were used to calculate odds ratios of care needs and their associations with time, mental healthcare consumption and medication use.

Results: Participants (n=2054) had on average 7.4 care needs per measurement and received 25.4 hours of care per year. Physical care needs are most prevalent and persistent and people with more care needs receive more mental healthcare. Care needs for psychotic symptoms and most social wellbeing related care needs decreased, while the chance of being overweight significantly increased with subsequent years of care. Several positive associations were found care needs and mental healthcare consumption as well as positive relations between care needs and evidence-based pharmacotherapy.

Conclusions: This longitudinal study present as novel approach in identifying care needs and their association with mental healthcare consumption and pharmacotherapy. Identification of care needs in this way based on ROM can assist daily clinical practice. A recovery-oriented view and a well-coordinated collaboration between clinicians and general practitioners together with shared decisions about which care needs to treat, can improve treatment delivery. Special attention is required for improving physical health in psychosis care which, despite appropriate pharmacotherapy and increasing care consumption, remains troublesome.

INTRODUCTION

Care needs

Psychotic disorders are characterised by symptoms such as hallucinations, delusions, disorganised thinking, poverty of speech, apathy and social withdrawal, which may be severe and persistent (1). Finding effective treatment for psychosis-related symptoms can be challenging (2). Up to one third of people with a psychotic illness experience persistent negative symptoms (3). Nearly half are faced with comorbid depression and substance abuse at some point during their life, with obsessive compulsive disorders and anxiety being present in 12% and 15% of the people respectively (4,5). With regard to physical health, cardio-metabolic risk factors are highly prevalent with half of the people with a psychotic illness meeting the criteria for metabolic syndrome (6). These physical risk factors contribute to a two- to threefold excess mortality rate compared to the general population (7). In regards to social wellbeing, loneliness is very common, potentially worsening psychotic symptoms (8). Homelessness and a lack of daytime activities are additional issues affecting social wellbeing (9,10). In an attempt to highlight these existing psychiatric symptoms, physical risk factors and issues affecting social wellbeing during clinical encounters, a treatment algorithm was developed which conceptualises these factors into different care needs (11). Care needs which remain unmet, meaning that patients do not receive any form of treatment for these needs, are strong predictors of reduced quality of life for people with severe mental illness (12,13). Many of these unmet needs tend to persist over subsequent years (4,5,10,14), emphasising both the difficulty and importance of providing adequate treatment. The aforementioned conceptualization of care needs enables investigating the prevalence of these needs in a large psychiatric population and their relation with provided care.

Evidence-based care consumption

In 2012, the second Dutch multidisciplinary guideline for schizophrenia was released (15), followed in 2018 by the standard of care for psychosis (16), both largely in line with National Institute for Health and Care Excellence (NICE) guidelines from the UK (17). These guidelines contain advice, recommendations and instructions for assessment, diagnosis and treatment of people with psychotic

disorders (15-17) Guideline concordant psychosis care can reduce symptoms, hospitalization and mortality rates in these patients (18-20). Studies suggest that despite their apparent utility, adherence to clinical guidelines in regular mental healthcare is suboptimal (21,22). For example, 60% of people with a psychotic illness diagnosed with metabolic disorders did not receive any form of guideline-recommended treatments for their condition (6). Furthermore, two-thirds of the care needs of patients with psychotic disorders in Dutch mental healthcare were not reflected in their treatment plans (23,24). This could in part be explained by insufficient resources, such as a lack of recommended interventions and trained practitioners in regional care (25). Another explanation could be that clinicians sometimes struggle to correctly assess all of their patients' needs. Routine Outcome Monitoring (ROM) is a method of using standard instruments to systematically monitor patients' health and wellbeing over time (26). It can be helpful in identifying care needs and providing input for a collaborative decision-making process. ROM also has the potential to monitor changes in these needs over time. It is important to get a better understanding of the relation between targeted evidence-based mental healthcare consumption and care needs of patients with a psychotic illness in order to offer optimal treatment. In this study, we will combine longitudinal ROM data with care consumption data and use existing treatment algorithms to identify care needs. Next, we will investigate how interventions and treatments offered in daily clinical practice are related to these care needs and how they develop over subsequent years.

Research aim

The first aim of this study is to systematically describe the prevalence of psychiatric, physical and social wellbeing related care needs of people with psychotic disorders. The second aim is to study changes in their care needs over subsequent years. The final aim is to explore the relationship between targeted evidence-based mental healthcare consumption and pharmacotherapy with care need outcomes.

METHOD

Data and participants

Data was obtained from an ongoing ROM cohort, called the Pharmacotherapy Monitoring and Outcome Survey (PHAMOUS), which screens people receiving care in various mental healthcare institutions in the Northern-Netherlands on a yearly basis (27). All patients with a psychotic disorder (DSM 5 diagnoses: 295.90, 295.40, 295.70, 297.1, 298.8 or 298.9) were selected. Included data was limited to the yearly screenings between 2012 and 2016, because data on the care patients received from 2017 and onwards was not yet available at time of analysis due to a new registration approach. People with a minimum of two consecutive screenings within a 9-to-15-month interval were included. For the analyses of longitudinal changes, participants had a minimum of two and a maximum of five assessments. Four institutions agreed to participate. The Medical Ethical Committee of the University Medical Center Groningen (UMCG) confirmed that anonymized PHAMOUS data can be used for scientific research (Research registration number 201700763, date January 9, 2018). The procedures of this study were in accordance with local legislation and the Declaration of Helsinki.

Care needs measures and algorithms

Three domains of care were assessed: psychiatric symptoms, physical health and social wellbeing. Each domain contained subcategories adding to a total of 23 care needs (see appendix 1).

Psychiatric care needs

Eight psychiatric symptoms were derived from the Positive and Negative Syndrome Scale (PANSS) (28), a semi-structured interview assessing clinical remission and the clinician-rated Health of the Nation Outcome Scale (HoNOS) (29), containing 12 items ranging from 0 (no problem) to 4 (severe problem).

Physical care needs

A total of eight physical care needs were defined. We used the Subject Response to Antipsychotics questionnaire (SRA-34) (30), a self-report questionnaire

measuring (side) effects of pharmacotherapy with 34 items on a 3-point scale (1 = no, 2 = yes, to some extent and 3 = yes, to a large extent). Physical parameters (i.e., blood pressure, BMI and waist circumference) and a blood sample (glucose, haemoglobin A1c, LDL cholesterol, triglycerides and prolactin) were used to assess physical care needs (27).

Social wellbeing care needs

A total of 7 care needs regarding social wellbeing were extracted from the HoNOS and Manchester Short Assessment of Quality of Life (ManSA; (31), a self-report questionnaire with 16 items on a 7-point Likert scale Ranging from 1 (could not be worse) to 7 (could not be better).

An overview of the 23 care needs is listed in table 2. (Combinations of) cut-off scores for all aforementioned instruments were used to calculate care needs as binary indicators (see appendix 1 for a more detailed overview). These cut-off scores were based on existing validated algorithms from guidelines and/or consensus from expert panel discussion groups which included psychiatrists, psychologists, nurse-practitioners and researchers (11).

Care consumption measures and evidence-based pharmacotherapy

Care consumption data was derived from the registration of Diagnosis Related Groups (DRGs). DRGs include all invoiced mental healthcare consumption from individual patients. For this study, DRG data was combined with PHAMOUS data by an external third party to guarantee an anonymized merged data file. First, the duration (in hours) of outpatient mental healthcare consumption per year was computed for every patient. In order to specify a proportion of evidence-based care consumption (in hours), an expert panel of 20 clinicians filled out an online questionnaire to determine which type of DRG care qualifies as evidence-based care for each care need (see appendix 2). Evidence-based pharmacotherapy was also dichotomized (see appendix 3) into present or absent for every applicable care need based on recommendations from the Dutch multidisciplinary guideline for schizophrenia (15), care standard for psychosis (16) and guidelines for specific care needs (e.g. the guideline for cardiovascular risk management Drenthe or the Dutch multidisciplinary guideline for depression (32)).

Analysis

Descriptive analyses were used to compare sociodemographic and clinical characteristics of the study sample with the overall PHAMOUS population (27). A multilevel analysis was conducted to estimate a model predicting care consumption based on the total amount of care needs. The associations between individual care needs and care consumption were analysed with generalized estimating equations models (GEE) (33). This method extends the generalized linear model (GLM) for clustered data and allows for correlations between repeated measures of individuals over time when analysing within and between-subjects' relationships (34). The models were constructed using binomial logistic regression with an exchangeable correlation structure and a robust estimation of variance (34). Every care need acted as a dichotomous dependent variable in separate logistic GEE analyses. Moment of assessment (i.e., 1, 2, 3, 4 or 5) was added as a scale weight variable in the GEE analyses to map the natural development of care needs over time (34). Care consumption (i.e., the total number of provided hours of mental healthcare per year) was also added as a scale variable and evidence-based pharmacotherapy was added as dichotomous factor with medication being prescribed as the reference category (no EVB-medication = 0 and EVB-medication = 1). Odds ratios were calculated for every care need and the predictors (i.e. time, care consumption and medication) were added to the GEE analyses to provide an indication of their effects on the change in odd ratio from one measurement to the next. Data from the SRA and several physical parameters were used to calculate care needs for anticholinergic side effects, sexual dysfunction and smoking. These data were not imputed because they were not missing at random. Subsequently, a smaller sample size was used when calculating care needs for anticholinergic side effects (n = 2395), sexual dysfunction (n = 2330) and smoking (n = 1335). Multiple imputations with predictive mean matching were used for imputing the other missing scale data for the HoNOS, PANSS, ManSA and the physical parameters of PHAMOUS (see table 1). A total of fifteen imputed datasets were generated and combined using Rubin's rule (35). The impact of the imputation on the results was evaluated by comparing the pooled effects to the effects of the original dataset. All statistical analyses were tested against the 0.01 significance level and performed using the Statistical Package of the Social Sciences (SPSS), version 27 (36).

RESULTS

Sample characteristics

A total of 2054 participants met the inclusion criteria for this study, who participated in a total of 5277 assessments (60.6% had 2 assessments, 22.1% had 3 assessments, 17.0% had 4 assessments and 0.3% had 5 assessments). The demographic characteristics of this sample are represented in table 1 and are comparable to the overall PHAMOUS population (27) except the slightly higher average age in this study (51 vs. 45 years). Participants had, on average, 7.4 out of the 23 care needs per measurement. Care need percentages ranged from 1.9% for self-harm to 90.2% for bodyweight (see table 2). Physical needs accounted for more than half of all care needs, with bodyweight (90.2%), hyperlipidemia (81.8%) and smoking (62.9%) being the most prevalent ones. Participants received on average 25.4 hours of mental health care per year (SD 27.2). The number of care needs positively predicted the amount of care consumption ($F(1,5277) = 523,997$, $p < .001$) (see figure 1). Participants' predicted care consumption is equal to $18.8 + .86 * (x \text{ care needs})$ hours of care consumption.

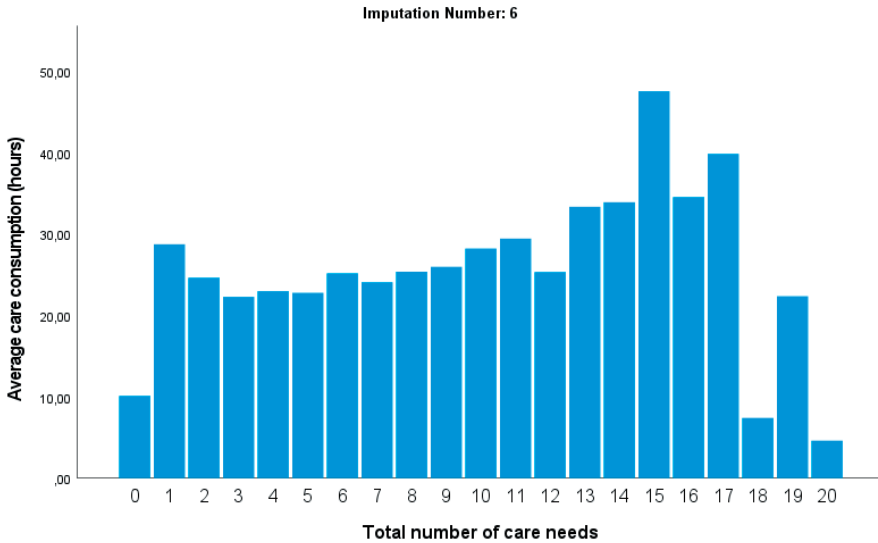
Table 1. Demographics of patients (n=2054)

Demographics	Mean (SD) or % (n)
Age years	51.0 (11.3)
Gender male	62.4 (1152)
Illness duration years	17.2 (14.4)
Diagnosis	% (n)
Schizophrenia	55.2 (1133)
Schizoaffective disorder	12.8 (264)
Substance induced	12.2 (251)
Psychosis NOS	2.5 (52)
Delusional disorder	2.0 (40)
Schizophreniform disorder	1.6 (33)
Definitive diagnosis missing	13.7 (281)
Number of care needs	Mean (SD)
Psychiatric (SD) (range 0-8)	1.7 (1.3)
Physical (SD) (range 0-8)	3.9 (1.4)

Social-wellbeing (SD) (range 0-7)	1.7 (1.6)
Total (SD) (range 0-23)	7.4 (2.8)
Care Consumption	Mean (SD)
Yearly care consumption in hours	25.4 (27.2)

Table 2. Percentage of patients with care needs (dichotomized) in all measurements (n = 5277)

Psychiatric care needs	% (n)
Positive symptoms	54.3
Negative symptoms	50.1
Substance use	23.8
Depressive symptoms	23.4
Anxiety	11.9
Agitation	6.6
Compulsive symptoms	2.6
Self-harm	1.9
Physical care needs	% (n)
Bodyweight	90.2
Hyperlipidemia	81.8
Smoking *	62.9
Anticholinergic side effects **	62.1
Hypertension	58.2
(Pre)diabetes type II	54.5
Sexual dysfunction ***	44.7
Movement disorder	42.3
Social-wellbeing care needs	% (n)
Social relationships	48.9
Sexuality	29.5
Housing conditions	22.5
Daytime activities	21.9
Intimacy	21.2
Personal safety	14.7
Family support	13.3

Figure 1. Total care needs and average care consumption

Association between care needs and time

The likelihood of experiencing psychiatric care needs remained the same on every measurement ($M = 53.3$ weeks) for most needs (see table 3). However, the likelihood of experiencing positive ($\beta = -.080$, 95% CI[-.138, -.021]) or negative symptoms ($\beta = -.077$, 95% CI[-.134, -.021]) decreased significantly with every measurement. The likelihood of being overweight ($\beta = .240$, 95% CI[.130, .351]) significantly increased with every measurement, whereas the likelihood of experiencing other physical care needs did not. The likelihood of experiencing social wellbeing related care needs changed the most, with the likelihood of having a care need for social relationships ($\beta = -.079$, 95% CI[-.138, -.020]), housing conditions ($\beta = -.108$, 95% CI[-.189, -.027]), daytime activities ($\beta = -.102$, 95% CI[-.176, -.029]) and personal safety ($\beta = -.150$, 95% CI[-.247, -.053]) significantly decreasing with every measurement.

Association between care needs and care consumption

Mental healthcare consumption was positively associated with half of all the psychiatric care needs (see table 3): the likelihood of experiencing depressive symptoms ($\beta = .007$, 95% CI[.004 to .009]), anxiety ($\beta = .006$, 95% CI[.003 to .009]),

agitation ($\beta = .006$, 95% CI[.002 to .010]) and self-harm ($\beta = .012$, 95% CI[.007 to .017]) increased with more hours of mental healthcare consumption. For physical care needs only the likelihood for being overweight ($\beta = .008$, 95% CI[.003 to .013]) increased significantly with more hours of mental healthcare consumption. The likelihood of experiencing social wellbeing care needs changed most with social relationships ($\beta = .004$, 95% CI[.001 to .007]), sexuality ($\beta = .004$, 95% CI[.001 to .007]), intimacy ($\beta = .004$, 95% CI[.001 to .007]), daytime activities ($\beta = .005$, 95% CI[.002 to .008]), personal safety ($\beta = .004$, 95% CI[.001 to .007]), and family support ($\beta = .006$, 95% CI[.002 to .008]), increasing significantly with more hours of mental healthcare consumption.

Association between care needs and evidence-based care and pharmacotherapy

When examining the association between evidence-based pharmacotherapy (see appendix 3) and psychiatric care needs, the likelihood of experiencing anxiety ($\beta = .680$, 95% CI[.492, .895]) and compulsive symptoms ($\beta = .586$, 95% CI[.138, 1.1034]) was significantly increased in people who received some form of medication for those specific care needs (see table 3). For physical care needs the likelihood of being overweight ($\beta = .355$, 95% CI[.099, .610]) and having (pre) diabetes type II ($\beta = 1.468$, 95% CI[1.235, 1.671]) increased in people that received some form of medication for those specific care needs. Conversely, the likelihood of having hyperlipidaemia ($\beta = -.295$, 95% CI[-.490, -.100]) significantly decreased in people using medication for hyperlipidaemia (see table 3). Differentiation of care consumption into evidence-based and other care consumption for every specific care need yielded no significant results (see appendix 2).

Table 3. Odds ratios of having a care need and associations with time (M = 53.3 weeks, SD 5.7), mental healthcare consumption and evidence-based pharmacotherapy in psychotic disorders.

Psychiatric care needs	β (OR)	β Time	<i>P</i>	β Consumption	<i>P</i>	β Medication	<i>P</i>
Positive symptoms	.151 (1.16)	-.080	.008*	.003	.033	.176	.009*
Negative symptoms	.148 (1.16)	-.077	.008*	-.002	.180	.061	.383
Substance use	-1.125 (0.33)	-.031	.373	.001	.544	.024	.780
Depressive symptoms	-1.323 (0.27)	-.092	.018	.007	.000**	.170	.073
Anxiety	-2.398 (0.09)	-.073	.165	.006	.001*	.693	.000**
Agitation	-2.608 (0.07)	-.118	.079	.006	.003*	.077	.591
Compulsive symptoms	-3.586 (0.03)	.057	.512	-.005	.251	.537	.009*
Self-harm	-3.805 (0.02)	-.286	.044	.012	.000**	-.075	.808
Physical care needs	β (OR)	β Time	<i>P</i>	β Consumption	<i>P</i>	β Medication	<i>P</i>
Bodyweight	1.508 (4.52)	.240	.000**	.008	.001*	.355	.006*
Hyperlipidemia	1.837 (6.28)	-.055	.183	-.002	.129	-.295	.003*
Hypertension	.329 (1.39)	.011	.703	-.002	.116	.175	.059
(Pre)diabetes type II	-.039 (0.96)	.086	.014	-.003	.047	1.468	.000*
Anticholinergic side effects +	.567 (1.76)	-.076	.081	.004	.035	.021	.798
Sexual dysfunction ++	-.255 (0.78)	-.022	.597	.003	.050	-.021	.816
Smoking +++	-.306 (0.74)	-.006	.870	.000	.899		
Movement disorder	.509 (1.66)	.035	.500	-.002	.363		
Social-wellbeing care needs	β (OR)	β Time	<i>P</i>	β Consumption	<i>P</i>		
Social relationships	.019 (1.02)	-.079	.008*	.004	.002*		
Sexuality	-.876 (0.42)	-.045	.189	.004	.005*		
Intimacy	-1.361 (0.26)	-.024	.507	.004	.006*		
Housing conditions	-1.105 (0.35)	-.108	.009*	.003	.022		
Daytime activities	-1.236 (0.29)	-.102	.006*	.005	.000**		

Personal safety	-1.585 (0.21)	-.150	.003*	.004	.004*
Family support	-1.986 (0.14)	-.017	.706	.006	.000**

The original data and pooled data were compared in order to test the impact on the outcomes (Supportive Information S2). Deltas between the pooled effects and the effects of the original dataset across full models varied between $\beta = .002$ and $\beta = .075$ indicating an adequate imputation.

DISCUSSION

This study distinguished 23 different care needs in three domains: psychiatric needs (eight needs), physical needs (eight needs) and social wellbeing needs (seven needs). Participants had on average 7.4 care needs per measurement of which more than half were physical. This is in line with previous research showing increased cardio-metabolic risks in people with a psychotic illness (7), which in part can be attributed to long-term use of antipsychotic medication (37). The prevalence of physical care needs in this study was relatively high compared to previous studies, examples being high bodyweight (90.2% vs 49.4%), hypertension (58.2% vs 38.7%) and smoking (62.9% vs 54.3%) (10). The prevalence rates did not change over subsequent years, except for an increasing chance of being overweight, thereby suggesting the nature of most physical care needs is persistent. The absence of significant relationships between physical care needs and mental healthcare consumption might be due to the majority of care consumption being psychiatric and psychosocial interventions (see appendix 2). Ideally, clinicians collaborate with general practitioners to address these physical needs which can also take place outside of mental healthcare settings such as community centers, gyms or assisted living accommodations. However, this is often not the case for people in psychosis care (23,24). No clear relation was found between evidence-based pharmacotherapy for specific physical care needs and a decrease of these needs over subsequent years, which suggests that treatment with pharmacotherapy alone might not be enough to address these needs.

Our findings about psychiatric care needs are more positive compared to physical care needs, as participants averaged 1.8 needs per measurement, with positive (54.33%) and negative (50.1%) symptoms as the most common needs. The chance of experiencing these core symptoms of a psychotic illness significantly decreased with every subsequent year. This is an interesting finding, since negative symptoms tend to be persistent and difficult to treat (14). Comorbidity with other psychiatric

symptoms such as anxiety, substance abuse, depressive and compulsive symptoms was present in less than a quarter of participants, which is comparable to previous findings (4,5,14). These needs are more persistent over time as chances for these psychiatric needs did not significantly decrease over time. Interestingly, pharmacotherapy was positively associated with an increased chance for some psychiatric care needs. It is important to note that our medication algorithm does not account for polypharmacy and overmedication which could be a potential explanation for these observed associations. When focusing on social wellbeing, participants averaged 1.7 care needs per measurement, with social relationships (48.9%) and sexuality (29.5%) as the most mentioned needs. Loneliness and a lack of meaningful relationships and intimacy are key issues affecting social wellbeing for people with a psychotic illness (8). The chances for most needs surrounding social wellbeing decreased over subsequent years, potentially indicating a more transient and less persistent nature compared to physical or psychiatric care needs. For example, needs surrounding personal safety or housing conditions might be prioritized during treatment because they are more acute. It is also possible people get accustomed to being alone over time.

In the Netherlands, people with less severe mental health issues generally receive care in basic mental health services, whereas people with a severe mental illness tend to receive care in specialized mental healthcare services (38). Participants in this study received on average 25 hours of outpatient specialized mental healthcare per year, which is about double the amount of care for people in basic mental healthcare services (38). Contrary to previous findings (39), more care needs were associated with more mental healthcare consumption. This could in part explain the positive associations between a higher chance of several psychiatric and social wellbeing care needs and more care consumption. In other words, participants received more care when they had more identified care needs, which is reflected by the increased chances of having these specific care needs on subsequent measurements.

Clinical implications

Appropriately allocating care in mental health care services among a diverse population is considered by some as the most important academic challenge of modern day mental healthcare (40). This study attempts to contribute to this challenge by proposing a methodology for identifying care needs and studying

their relation with care consumption. Our results confirm earlier findings in which people with psychotic disorders are often faced with multiple persistent physical care needs, accompanied by one or both core symptoms of psychosis and a need for social connection and intimacy. These findings justify investing in lifestyle or social wellbeing related interventions such as peer support groups in the form of eating clubs (41). On an individual level, care needs identified by ROM can serve as useful input during consultations. When they are combined with treatment recommendations, for example by using a computerized clinical decision aid, they have the potential to facilitate shared-decision making and help patients and mental health care workers to decide together on a course of treatment (42). Our analyses can also be utilized to assess needs and care provisions in teams or institutions. For example, in this study a majority of care needs are of a physical nature, yet only a small fraction of the provided care is specifically aimed to treat those conditions (see appendix 2). It is important to note that a perfect fit between identified care needs and appropriate care, in which all needs are addressed in treatment, is likely not feasible, considering the amount of comorbidity as demonstrated in this study. Moreover, identified care needs might not always be perceived as an actual need by patients, which makes the implementation of treatment interventions a strategic choice, ideally collaboratively explored and decided on by clinicians and patients together.

Strengths and limitations

A strength of this study is the innovative way in which ROM was used to identify care needs and monitor their changes over time, potentially acting as an example for other institutions and future research. With over 2000 participants yielding more than 5000 measurements over a four-year period, this study features a unique clinical sample. There has been a tendency in previous research to focus on either psychiatric symptoms or cardiometabolic risk factors. To the best of our knowledge, this is the first study in psychosis research attempting to identify a broad range of potential care needs and their longitudinal development on the psychiatric, physical as well as social wellbeing related domain. By combining ROM data with care consumption data, this study was able to identify various associations between care needs and (evidence-based) care consumption. An important limitation of this study is that our care consumption data only includes

outpatient mental healthcare consumption. The degree to which they apply also to inpatient settings is yet to be studied. Moreover, because people with more care needs tend to consume more care these associations have to be interpreted with caution. This study was not set up to investigate prospective associations, so it remains unclear if for instance more care needs lead to more care consumption or vice versa. Some care needs such as bodyweight and blood pressure are known to be correlated with age. Due to the limitations of a cohort study, it could not be determined how much of this increase was beyond what can be expected in the general population over time. This study is focused on patients receiving long-term psychiatric care, given the diagnostic criteria and the inclusion of only people with multiple measurements. This is also reflected in the higher mean age of participants included in this study compared to the overall PHAMOUS population (51 vs. 45 years), which should be taken into account when generalizing these results, for instance when comparing them to first episode populations. It is also important to note that we used a clinical conceptualization of care needs, identified with existing treatment algorithms and based on routine outcome monitoring (ROM) data. Only part of the data was obtained by self-report questionnaires and therefore does not always take into account the subjective experience of needs. For example, some participants might smoke or be overweight without perceiving this as an issue needing treatment. The identification and conceptualization of care needs serves a clinical purpose, but a collaborative effort based on shared decision-making is needed. Future research could opt to conceptualize care needs differently, for example on continuous scales, potentially making the analyses more sensitive to change (43).

Conclusion

This longitudinal study identified psychiatric, physical and social wellbeing related care needs with existing treatment algorithms based on yearly obtained Routine Outcome Monitoring (ROM) data combined with care consumption data. Physical care needs were most prevalent and persistent. Positive and negative symptoms were the most common psychiatric care needs, but the chance of experiencing these needs decreased with subsequent years of care. Care needs related to social wellbeing had a more transient character. As might be expected, people with the highest needs received the most mental healthcare potentially explaining

the positive relation between many of these needs with care consumption. The prime focus in psychosis care used to be on recovery of psychiatric symptoms but is shifting more towards recovery-oriented care encompassing both personal recovery and social wellbeing (44). Ideally, the responsibility for physical care should be an interplay between clinicians and general practitioners. Defining and identifying care needs based on ROM has the potential to assist daily clinical practice and help institutions with care allocation in order to accommodate people's care needs on these different domains.

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Appendix 1. Algorithms for identifying care needs

Psychiatric care needs	Instruments	Cut-off Scores
Positive symptoms	PANSS (P1,P2, P3, P4, P5, P6 & P7), HoNOS	P1>3, P2>2, P3>3, P4>4, P5>4, P6>3, P7>3. P1,P3,P4,P5,P6<P7: min 4 items score 3. HoNOS>1. P1-P7 if 1 or more>3. P1,P2,P3,P6 minimum 2 items score 3. P1-P7 min 3 items score 3. HoNOS>2. In case ≥1 or more of these apply
Negative symptoms	PANSS (N1, N2, N3, N4, N5, N6 & N7)	N1>3, N4>3, N6>3. Both N1,N4,N6=3. N1-N7 if 1 or more>3. If 2 items of N1,N2,N3,N4 score 3. N1-N7 min 3 items score 3. In case ≥1 or more of these apply
Substance Use	HoNOS (item 3)	A6>3. HoNOS>1. In case ≥1 or more of these apply
Depressive symptoms	PANSS (A6), HoNOS (item 7)	HoNOS> 2 & C
Anxiety	PANSS (A2), HoNOS (item 8)	HoNOS> 0 & < 3. HoNOS > 2
Agitation	HoNOS (item 1)	HoNOS> 1
Compulsive symptoms	HoNOS (item 8)	A2 > 3, HoNOS > 2 & B. In case ≥ 1 or more of these apply
Self-harm	HoNOS (item 2)	HoNOS > 1
Physical care needs	Instruments	Cut-off Scores
Bodyweight	SRA (item 3 & 32), BMI, abdominal circumference	SRA, item 3: score 1 or 2, item 32 score 1 or 2. BMI > 25 kg/m ² . AC > 88 cm (f), > 102 cm (m)
Hyperlipidemia	Low-density lipoprotein (lab test)	LDL ≥ 2,5 mmol/L and/or TG N > 2,2 mmol/L
Smoking	Anamnesis	Yes
Anticholinergic side effects	SRA (item 9, 12, 16 & 20)	SRA, if ≥ 1 score of 2 or if ≥ 2 score of 1
Hypertension	Blood pressure (lab test)	Blood pressure ≥ 130/85
(Pre)diabetes type II	Glucose (lab test)	Glucose ≥ 5,6 and/or hemoglobin A1c > 39 (>5,7%)
Sexual dysfunction	SRA (item 15, 21, 35)	SRA, item 15: score 1 or 2, item 21: score 1 or 2, item 35: score 1 or 2 (f). In case ≥ 1 or more of these apply
Movement disorder	Movement test, SRA (item 18 & 28)	Movement check diagnosis: dyskinesia, dystonia, parkinsonism, akathisia. SRA, item 18: score 1 or 2, item 28: score 1 or 2

Social-wellbeing care needs	Instruments	Cut-off Scores
Social relationships	ManSA (item 12), HoNOS (item 9)	ManSA < 4, HoNOS > 1. In case ≥ 1 or more of these apply
Sexuality	ManSA (item 15)	ManSA < 4
Housing conditions	ManSA (item 2 & 3), HoNOS (item 11)	ManSA, item 2 < 4, item 3 < 4, HoNOS > 1. In case ≥ 1 or more of these apply
Daytime activities	ManSA (item 4), HoNOS (item 12)	ManSA < 4, HoNOS > 1. In case ≥ 1 or more of these apply
Intimacy	ManSA (item 14)	ManSA < 4
Personal safety	ManSA (item 7, 8 & 9)	ManSA, item 7 = yes, item 8 < 4, item 9 = yes
Family support	ManSA (item 13)	ManSA < 4

PANSS = Positive and negative symptom scale (semi-structured interview), HoNOS = Health of the nation outcome scale (clinician-rated),

SRA = Subject response to antipsychotic questionnaire (self-report), ManSA = Manchester short assessment of quality of life (self-report)

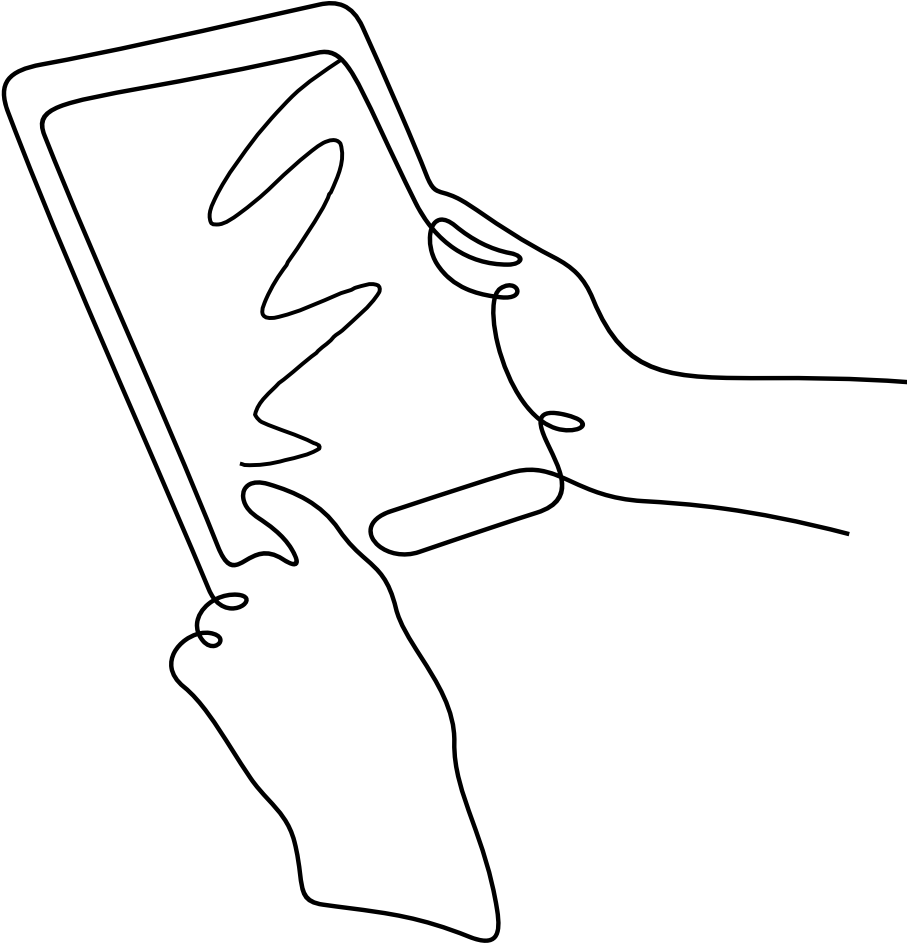
Appendix 2. Diagnosis related group codes for applicable care needs

Description	Care Needs
Electroconvulsive therapy	Positive symptoms, depressive symptoms
Creative therapy	Negative symptoms, depressive symptoms, agitation, anxiety, self-harm, social relationships
Activating counseling	Positive symptoms, negative symptoms, depressive symptoms, substance abuse, anxiety, social relationships
Physiotherapy	Bodyweight, (pre)diabetes type II, movement disorder
Behavioral therapy	Positive symptoms, depressive symptoms, anxiety, OCD
Light therapy	Depressive symptoms
Psychotherapy	Depressive symptoms, anxiety, OCD, self-harm
Communicative treatment	Negative symptoms, depressive symptoms, anxiety, social relationships, intimacy, family support
Psychomotor therapy	Negative symptoms, depressive symptoms, anxiety, social relationships, self-harm, personal safety, positive symptoms
System Therapy	Depressive symptoms, social relationships, intimacy, family support
Cognitive behavioral therapy	Positive symptoms, negative symptoms, depressive symptoms, anxiety, OCD

Appendix 3. Diagnosis related group codes for applicable care needs

Care Needs	Medication	Evidence-based medication steps
Positive symptoms	aripiprazole, bromopride, chlorprothixene, clozapine, flupentixol, haloperidol, levopromazine, olanzapine, periciazine, perphenazine, pipamperone, pimozide, promazine hydrochloride, quetiapine, risperidone, sulpiride, triflupromazine, zuclopenthixol, bromopride, fluphenazine, flupentixol, fluspirileen, penfluridol	1) increase dose antipsychotic 2) switch to different antipsychotic 3) start clozapine 4) addition antipsychotic to clozapine 5) addition lamotrigine, memantine or lithium to clozapine
	aripiprazole, bromopride, chlorprothixene, clozapine, flupentixol, haloperidol, levopromazine, olanzapine, periciazine, perphenazine, pipamperone, pimozide, promazine hydrochloride, quetiapine, risperidone, sulpiride, triflupromazine, zuclopenthixol, bromopride, fluphenazine, flupentixol, fluspirileen, penfluridol	1) reduce dose antipsychotic 2) polypharmacy reduction 3) switch to antipsychotic with lower D2 affinity 4) addition antidepressant 5) addition lamotrigine to clozapine
Substance use	aripiprazole, clozapine, olanzapine, paliperidone, quetiapine, risperidone	1) second generation antipsychotic
Depressive symptoms	imipramine, amitriptyline, clomipramine, nortriptyline, venlafaxine, mirtazapine, citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, trazodone, moclobemide, tranylcypromine, phenelzine, escitalopram, duloxetine, bupropion, hyperiplant	1) antidepressant 2) Reduce dose antipsychotic 3) switch to antipsychotic with lower D2 affinity
Anxiety	lorazepam, bromazepam, chlordiazepoxide, midazolam, clobazam, oxazepam, prazepam, temazepam, lormetazepam, nitrazepam, zolpidem, lorazepam, bromazepam, chlordiazepoxide, midazolam	1) anxiety medication
Agitation	lorazepam, clozapine	1) lorazepam and or clozapine
Compulsive symptoms	clomipramine, fluoxetine, citalopram, escitalopram, fluvoxamine, paroxetine, sertraline, venlafaxine	1) compulsive symptoms medication
Self-harm	clozapine	1) clozapine

Bodyweight	aripiprazole, amisulpride, ziprasidone, haloperidol, pimozide, perphenazine, metformin	1) switch to high potent first generation antipsychotic 2) metformin
Hyperlipidemia	lipid modifying agents	1) lipid modifying agents 2) no olanzapine, clozapine or quetiapine
Hypertension	antihypertension medication	1) antihypertension medication
(Pre)diabetes type II	antihyperglycemics, metformin	1) antihyperglycemics 2) metformin
Anticholinergic side effects	aripiprazole, bromopride, chlorprothixene, clozapine, flupentixol, haloperidol, levropromazine, olanzapine, periciazine, perphenazine, pipamperone, pimozide, promazine hydrochloride, quetiapine, risperidone, sulpiride, triflupromazine, zuclopenthixol, bromopride, fluphenazine, flupentixol, fluprofen, penfluridol	1) reduce dose antipsychotic 2) switch to different antipsychotic
Sexual dysfunction	aripiprazole, bromopride, chlorprothixene, clozapine, flupentixol, haloperidol, levropromazine, olanzapine, periciazine, perphenazine, pipamperone, pimozide, promazine hydrochloride, quetiapine, risperidone, sulpiride, triflupromazine, zuclopenthixol, bromopride, fluphenazine, flupentixol, fluprofen, penfluridol	1) reduce dose antipsychotic 2) switch to antipsychotic with lower D2 affinity



Chapter 5

Qualitative analysis of clinicians' perspectives on the use of a computerized decision aid in the treatment of psychotic disorders

Lukas O. Roebroek, Jozanneke Bruins, Albert Boonstra, Philippe A.E.G. Delespaul, Stynke Castelein

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ABSTRACT

Background: Clinical decision aids are used in various medical fields to support patients and clinicians when making healthcare decisions. Few attempts have been made to implement such tools in psychiatry. We developed Treatment E-Assist (TREAT); a routine outcome monitoring based computerized clinical decision aid, which generates personalized treatment recommendations in the care of people with psychotic disorders. The aim of this study is to investigate how TREAT is used and evaluated by clinicians and how this tool can be improved.

Methods: Clinicians working with TREAT during a clinical trial were asked to participate in semi-structured interviews. The Unified Theory of Acceptance and Use of Technology (UTAUT) was used as a sensitizing theory to structure a part of the interview questions. The transcripts were analyzed using inductive thematic analysis to uncover the main themes.

Results: Thirteen clinicians (mean age: 49) of which eight psychiatrists and five nurse practitioners, participated in this study. Eight clinicians experienced TREAT as beneficial, whereas five experienced no additional benefits. Thematic analysis revealed five themes surrounding usage and evaluation of TREAT, views on TREAT's graphic representation of routine outcome monitoring results, guideline based treatment recommendations, contextual factors, effects on patients and effects on shared decision-making. Performance and effort expectancy were perceived as high by clinicians. The facilitating conditions were optimal and perceived social influence was low.

Conclusion: This article presents a qualitative evaluation by clinicians of a computerized clinical decision aid in psychosis care. TREAT was viewed by most clinicians as beneficial during their consultations. The graphic representation of routine outcome monitoring results was well-appreciated and provided input to discuss treatment planning with patients. The treatment recommendations did not change most treatment decisions but supported clinical reasoning. However, some clinicians were unconvinced about TREAT's benefits. The delivery, applicability and the availability of resources require improvement to increase TREAT's efficacy. Not all patients responded well to TREAT but the observed facilitation of shared decision-making is promising. All four predictors of the Unified Theory of Acceptance and Use of Technology were positively evaluated by the majority of clinicians.

INTRODUCTION

Decision aids

When patients and clinicians draft treatment plans, there are many things to consider. There may be multiple options with no clear, best choice. Clinical decision aids (CDAs) aim to facilitate and improve therapeutic decision-making. They help professionals and patients agree on important treatment options (1). CDAs do so by assessing needs and providing evidence-based information about treatment options including risks and benefits (1). Despite the effectiveness of these tools (2), their integration in daily clinical practice remains limited (3,4). Less than half of all CDAs are still used after the experimental evaluation period (4). This is due to a lack of funding or endorsement by organizations, because the tools are out of date or do not fit the existing care processes (4). Aligning CDAs with guidelines, care standards, clinical policies, existing infrastructure and workflows can augment their uptake within organizations (5). Often, clinicians remain unconvinced of the benefits of CDAs (6), arguing that they do not agree with their content and use or simply lack time to implement them in their daily clinical practice (4). Therefore, it is important to involve clinicians in different stages of development of new CDAs and critically evaluate their functionality.

TREAT

CDAs could benefit psychiatric care, as patients generally have multiple complex care needs, while clinicians often make treatment decisions based on personal preferences (7). CDAs can reduce the knowledge-gap between available treatments and potential outcomes. They can improve reflection about personal preferences by providing feedback on risk and benefits of specific interventions, for example when deciding on psychiatric medication (2). Unfortunately, CDAs are poorly implemented and rarely used in psychiatric care. A systematic review of 105 clinical trials of CDAs only included three studies in mental health (2). These tools reduced decisional conflict and increased knowledge about treatment options for patients with depressive (8) and post-traumatic stress disorders (9). One CDA facilitated shared decision-making (SDM) for patients with psychotic disorders (10). To improve adoption of CDAs in psychosis care, Lentis Psychiatric Institute developed a computerized CDA: Treatment E-Assist (TREAT) (11). TREAT is the first

CDA in psychosis care that combines routine outcome monitoring (ROM) data with current treatment guidelines and care standards to provide clinicians and patients with personalized evidence-based treatment recommendations. Care providers in the Northern-Netherlands use an extensive ROM-screening in psychosis care called the Pharmacotherapy Monitoring and Outcome Survey (PHAMOUS) (12). Routine outcome data are ideally used to draft treatment plans during annual consultations. There is no formal procedure for integrating these data into daily clinical practice. As such the way information from PHAMOUS is directly used to guide treatment varies between institutions, teams and clinicians. Although PHAMOUS is effective in identifying care needs, these needs are not always met with appropriate care (13,14). TREAT was designed to bridge the gap between ROM-data and treatment choice by offering customized treatment recommendations to discuss during the annual treatment plan evaluations. TREAT is evaluated on its clinical effectiveness in improving care in a multicenter study.

Research aim

The focus of this study is on the usage and evaluation of TREAT by clinicians. Three aims were formulated: 1) assess how clinicians use TREAT during consultations, 2) gain greater understanding in user acceptance by investigating how clinicians evaluated TREAT, and finally 3) collect information on how to improve the application for future use.

METHOD

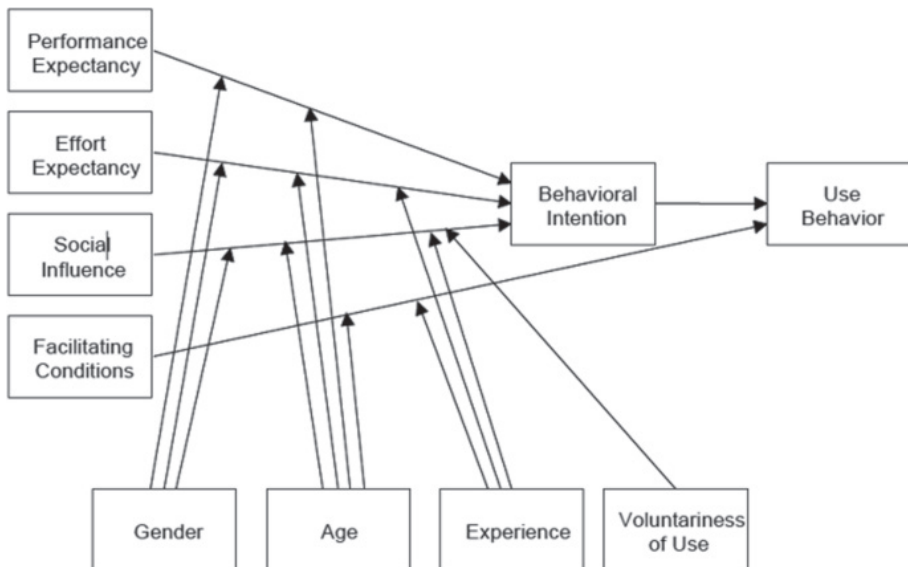
Study setting and participants

During the trial, clinicians were asked to use TREAT, each with four different patients, during their annual treatment plan evaluations. In total, 33 clinicians enrolled in the trial of which 27 actually worked with the TREAT application. In-depth interviews were conducted with those clinicians who used TREAT with at least three different patients. In total, 13 clinicians who met this criterion were approached and agreed to participate. They worked in 11 different flexible assertive community treatment (FACT) teams of four mental healthcare institutions.

Study design

A descriptive qualitative design was used to gain insights into the experiences and attitudes of clinicians who worked with TREAT. The Unified Theory of Acceptance and Use of Technology (UTAUT, Figure 1) (15) was used as a sensitizing theory to structure our semi-structured interview guide, as shown in additional file 1. This model is a reference to explore an individual's intention to adopt a technological innovation in an organizational setting. In the UTAUT model performance expectancy, effort expectancy, social influence and facilitating conditions predict usage behavior (15). These predictive factors are moderated by gender, age, experience (occupation and years working in psychosis care) and voluntariness of use (15). Additional questions structured in accordance with our research aim were added to the interview guide (see additional file 1) such as "In what way did you use TREAT?" or "What was the effect of TREAT on your clinical encounters?"

Figure 1



Unified theory of acceptance and use of technology

Data collection

All data was collected between July and September of 2019. Clinicians were invited through telephone calls to participate in this study and interviews were planned with those who were willing to participate. All interviews took place in the office of clinicians. The assessment started with a brief introduction to explain the goals of the interview and to sign the informed consent. Subsequently, the semi-structured interview was conducted by the first author (LR) based on the interview guideline. All questions were open and the researcher asked in-depth questions to further elucidate unclear or ambiguous information. The interviews lasted between 15 and 45 min. All interviews were digitally recorded and transcribed verbatim. Our goal was to identify as many relevant themes as possible. No new information or themes emerged after 13 interviews after which data saturation was assumed and data collection was stopped (16).

Data analysis

We analyzed the data using an inductive thematic analysis approach (17). With the use of the qualitative data analysis software of ATLAS Ti version 8.4, every transcript was coded line-by-line by the first author to identify patterns and gaps in the data. Two hundred seventy-three codes were identified. Using an inductive approach, the research team identified themes from the codes (18). Finally, the research team discussed the themes on relevance until consensus was reached.

RESULTS

We interviewed 13 professionals: eight psychiatrists and five nurse practitioners. The average participant age was 49, seven were female and their average experience with working in psychosis care was 17 years (Table 1). Eight clinicians experienced the application as overall benefiting their clinical encounters, whereas five experienced no or even a negative impact on their daily clinical practice. The research group identified five recurrent themes in the interviews: 1) graphic representation, 2) guideline based treatment recommendations, 3) contextual factors, 4) effects on patients and 5) effects on shared decision-making. These themes were appraised differently by the respondents and provided new insights into the way TREAT was used during consultations and contained feedback that can be used to improve TREAT for future use.

Table 1 Clinician demographics

Clinician	Occupation	Age range	Years in psychosis care
1	Psychiatrist	61–65	23
2	Psychiatrist	41–45	3
3	Nurse practitioner	41–45	21
4	Psychiatrist	66–70	33
5	Psychiatrist	41–45	11
6	Nurse practitioner	41–45	20
7	Psychiatrist	56–60	23
8	Psychiatrist	36–40	5
9	Nurse practitioner	36–40	20
10	Psychiatrist	51–55	19
11	Nurse practitioner	61–65	15
12	Psychiatrist	41–45	15
13	Nurse practitioner	46–50	12

Theme 1: Views on TREAT's graphic representation

Before the introduction of TREAT, ROM results were summarized in a letter to the clinicians and the general practitioner (i.e. 'ROM-letter'). It contains a written description of the ROM results. The TREAT application presents ROM results graphically and structures it in three areas (symptoms, physical health and psychosocial wellbeing, Figure 2). This representation was frequently discussed. The majority of the respondents indicated that, compared to the ROM-letter, TREAT reports were an improvement. Data is better structured and more appealing. The graphs made it easier to identify and interpret issues and the visualization improved the discussion with patients. One clinician noted:

Figure 2



Example of the graphic data representation

"It's a really good instrument to interpret the ROM-results and to take action if needed. It makes things a lot easier. With the ROM-letter, "you had to figure out what should be discussed with the patient, and which matters were less important. With TREAT it's much more obvious, so yeah, it's much easier." [C1]

Another clinician emphasized the visualization of outliers in the results:

"TREAT is very user-friendly and the graphs also make it very visual. People were able to really see the outliers in their results, which gives me the opportunity to specifically discuss them. It gives people guidance and support during the consult." [C8]

However, some clinicians indicated that TREAT added little value to their already structured routine:

"Let me start by saying that our ROM-letter, which we have been using for years, has a clear overview of all ROM results. Therefore, I am already used to evaluate these

results systematically with my patients. With TREAT this remains the same albeit in a different visual representation with graphs and treatment recommendations.” [C12]

While some clinicians felt TREAT complicated their routine:

“I always used the ROM-letter myself to check for any particularities, somehow there always seemed to be less than with TREAT. Now the focus is on many more areas, so you almost need to prepare ahead of time.” [C5]

Overall, the representation of the ROM-results was well-appreciated by most clinicians and seen as an improvement compared to the previous ROM-letter. Graphic representation of the ROM-results made pressing issues in treatment more visible and therefore easier to discuss. Based on the UTAUT model, TREAT's graphical representation positively affected the predictive factors of effort and performance expectancy.

5

Theme 2: Views on TREAT's treatment recommendations

TREAT offers several treatment recommendations (Figure 3) for clinicians to consider with their patients. Some clinicians found these recommendations helpful:

“That's what I like about TREAT; you are not forced to follow for example a recommendation to start an anti-depressant in case of persistent negative symptoms. You just discuss it, like is this something you would prefer or not. Maybe you both decide to try something else. Either way the recommendation is still valid, it's just not mandatory.” [C6]

However, others found the recommendations bothersome or felt pressured:

“I mean, I know it's not mandatory to follow the recommendations, but it still feels that way. Sometimes, you're just happy that somebody is using the medication you prescribe at all, and then you get the recommendation to switch the medication. TREAT seems to always tell you that it's not good enough. It's never good enough.” [C13]

Figure 3



Example of treatment recommendations

Even though the tone of the treatment recommendations was experienced in different ways, all clinicians agreed that the actual content of the recommendations was sound. However, opinions on the applicability varied. Several clinicians experienced the suggestions as generic and comprehensive, sometimes even too comprehensive. Not all recommendations were suited for the clinical complexity of the patient, or had already been tried before:

“The treatment recommendations are sound but you always need to tailor them to a specific patient or circumstance and see if they still apply.... It’s difficult because sometimes certain recommendations from guidelines have already been tried or are not applicable anymore.” [C2]

Although several clinicians raised the issue of utility, most of them had checked the utility and relevancy of the recommendations for each individual patient and found ways to incorporate them into their consultations. The recommendations were used to evaluate previous steps and to discuss and decide on current treatment plans, as this respondent explained:

"TREAT is helpful in aligning treatment with the evidence-based recommendations. It can be used to start a conversation about treatment options and help explain why alternative treatment options might be more preferable." [C11]

Other clinicians used the recommendations to discuss possible future steps in the treatment process:

"TREAT also provides information about possible future steps in treatment such as for example electroconvulsive therapy. If recommendations are presented on a screen it feels more natural to address it as an option. You can inform patients of different options in case the current treatment doesn't work." [C8]

However, some clinicians did not see the recommendations as beneficial. They argued that they were well aware of the content of existing guidelines and therefore did not need an overview of the different guideline-recommended treatment options, as this respondent stated:

"TREAT was not beneficial in reminding me of new things we could try for a specific problem. It's not really a lack of knowledge I experience when drafting a treatment plan or when starting a new treatment." [C12]

Some respondents even experienced the recommendations as irritating:

"I feel guidelines are necessary as a foundation but we can also assume they are well-known. To build a system just to beat people over the head with guidelines defeats its purpose. It irritates." [C10]

Overall, opinions on the recommendations varied. Some respondents actively used the recommendations during their consultations while others felt no need for guideline implementation. Multiple suggestions were made to shorten the text and to make recommendations more personalized. It is important to look for ways to improve these recommendations, as a perceived lack of utility could potentially prevent clinicians from working with TREAT after this clinical trial.

Theme 3: Views on TREAT's contextual factors

All clinicians agreed that TREAT was properly imbedded into the existing technical infrastructure of the electronic patient record. Therefore, the facilitating factor

referred by the UTAUT model was perceived as optimal and enhanced TREAT's use. Clinicians who experienced TREAT as benefiting their practice found it easier to incorporate the application into their routines. Teams that used a strict screening routine, organized processing of the screening data and structured scheduling of treatment plan evaluations, were most successful at implementing TREAT. Some teams used the opportunity of the TREAT study to improve their screening process and feedback procedure, as this clinician highlighted:

"We chose to participate in the TREAT study and to make TREAT the driving force behind our evaluations and yearly screenings." [C9]

Getting used to a tool such as TREAT, even if ultimately intended as a time-saver, takes time (15). Most teams indicated, however, that they simply did not have that time, as they were understaffed. Some clinicians indicated that the TREAT application made their consultations more time efficient. However, the majority experienced either no difference or reported increased consultation times. Most clinicians had to become familiar with TREAT and find ways to use it effectively during consultations:

"You really need to work with it [TREAT] a few times because you can get questions for which you were not prepared or reminded of things you might have missed." [C7]

Apart from novelty, TREAT also increased consultations times by bringing up a larger array of topics for discussion:

"I think my consultations became longer, because I noticed some time shortage. Therefore, you probably take or just need some more time to discuss all the results. It depends of course, on what ends up in TREAT. If someone has few problems you are quicker to discuss everything." [C12]

This is in part because the PHAMOUS screening is extensive and patients often experience issues in multiple areas. Furthermore, an incomplete screening was mentioned several times as a limiting factor. Clinicians sometimes chose not to use TREAT during a consultation because questionnaires were missing. In addition, more than half of the clinicians indicated that some of the recommended interventions were not part of the available treatment resources within their team. In some teams, nearly all of the recommended interventions were unavailable. Psychomotor therapy (PMT) was mentioned most frequently as a missing resource,

followed by cognitive behavioral therapy (CBT), eye movement desensitization and reprocessing (EMDR) and individual placement and support (IPS). Clinicians generally ignored unavailable recommendations during consultations, thereby potentially decreasing TREAT's efficacy. In some cases, TREAT motivated clinicians to recruit professionals for missing resources elsewhere in their organization:

"I really feel a lot of the added value lies in the fact that we are used to recommending treatments we have available. TREAT reminds you of treatments you do not have available directly, so you can try and find those treatments elsewhere within the organization." [C8]

Compared to most CDAs in fields such as oncology, cardiology or orthopedics (2), psychiatry differs from settings in which CDAs have found mass adoption because care for patients in FACT teams is mostly integrated in long lasting recovery based processes (19). Treatment decisions fit in an approach in which timing of interventions is important. Interventions should be available at various times throughout the treatment process. Moreover, psychotic illness is periodic and the decision-making process should match this process-based variability. It was mentioned several times that it is not always straightforward to turn treatment recommendations into behavioral changes for this patient group:

"Most people have been in care for a long time and suffer from several disabilities. Sometimes you are able to initiate something new by putting in a lot of effort, but sometimes it just does not work because some patients have been doing things in a certain way for so long it's difficult to motivate them to try things in a new way." [C7]

On the other hand, some clinicians actually used TREAT as a driving force to try new steps in treatment without postponing them:

"I think it [TREAT] helps clinicians to stay closer to and be more professional in chronic treatment while remaining evidence-based without postponing the next step in treatments." [C8]

To summarize, structured and complete ROM screenings facilitate the use of TREAT. Consultations need to be strictly planned after screenings and might take more time. Missing treatment resources within teams can lower the efficacy of TREAT and hamper its implementation.

Theme 4: Views on TREAT's effects on patients

The effects of TREAT on individual patients were a recurring theme. The extent to which patients were engaged in the use of TREAT varied. In most cases, patients and clinicians sat together in front of a computer screen to review the TREAT report. However, some clinicians preferred to use the printed version. Overall respondents noticed that sharing information with TREAT did not work equally well for all patients. Some had cognitive problems and were easily overwhelmed by the complexity of the data presented in the application:

"I noticed that if patients are not able to process a lot of information at the same time or if they are very much stuck in their own line of thinking, TREAT's systemic approach doesn't really work that well." [C2]

Most clinicians indicated that they did not notice significant changes in the therapeutic relation with their patients when using TREAT. However, some clinicians did:

"We think that the traditional treatment relationship between patient and clinician is fundamentally changing, it is becoming more horizontal, not in every aspect but in many. That is where it is supposed to go. I really think TREAT can facilitate this because it increases commitment and a feeling of ownership." [C4]

Another clinician noticed a greater sense of ownership for patients while using TREAT:

"It really has to do with ownership of the data. If I have a ROM-letter with a lot of text, it feels like I own the data. With TREAT there is a subtle nuance in how it feels, like you give the patient more ownership and make them the owner of the data." [C2]

Most clinicians viewed TREAT as an effective tool to engage in conversation with patients about specific areas of interest or suggested treatment recommendations:

"You can show your patients the different treatment options during the consultation and explain the risks and benefits. I see it as a useful tool to engage in a conversation about the available treatment options." [C3]

It was often mentioned that TREAT prevents you from missing certain issues during consultations. This opens up the opportunity to discuss these issues with patients, as this respondent revealed:

"Of course, that's the beauty of this system. TREAT suggests things that you otherwise might have forgotten or wouldn't have thought of. Sometimes it can be used to engage in conversation. For instance saying something like: "According to the guidelines, you would have to start with an antidepressant. What do you think? Oh, you don't want another pill? Okay." [C6]

Several clinicians indicated that it became easier to discuss intimate topics because they were explicitly stated in TREAT. One respondent pointed out sexuality as an example:

"For example sexuality. That is not something you would immediately discuss, I mean you should of course, so that is my fault, but with TREAT, it is explicitly stated. Also intimacy. It therefore brings itself up, which makes you talk about it. So that's an improvement." [C4]

Some clinicians expressed concerns that TREAT focusses more on problems instead of strengths. Highlighting the positive trends and aspects of treatment was mentioned several times as a potential improvement. Most clinicians have a recovery-oriented view on patient care, which sometimes contradicted the alarming nature of TREAT as this respondent explained:

"Our intention in our patient contact is to try to focus on recovery and strengths. However, TREAT draws the attention mostly to the negative points." [C13]

In a few cases, patients experienced TREAT as confrontational and it even scared some:

"Sometimes I would notice a negative atmosphere, caused by the results and how they are displayed. That's because it mostly highlights problems which pop up in red graphs. That scared some patients." [C12]

In sum, some clinicians noticed some patients did not respond well to TREAT because it confused or scared them. However, clinicians were able to use TREAT effectively during consultations with most of their patients. Important and sensitive issues became apparent and were therefore less likely to be forgotten which strengthened clinicians' performance expectancy as referred to in the UTAUT model.

Theme 5: Views on TREAT's effects on shared decision-making

A majority of clinicians indicated that TREAT supported their clinical reasoning. It did not change the outcome of most treatment decisions, but improved the way these decisions were made. Even though clinicians held different opinions regarding the benefits of TREAT, nearly all of them agreed that it contributes to shared decision-making (SDM):

"It [TREAT] did have a positive influence on shared decision-making. You have multiple options to choose from. That was most obvious with things like negative symptoms. You can tell someone music therapy or cognitive behavioral therapy is available, but scrolling through these options together makes it easier for patients to say: 'that doesn't suit me, but this is something I'd like to try.'" [C8]

Another clinician provided a practical example of TREAT contributing to SDM during a consultation:

"It [TREAT] improves your thinking. For example with a patient suffering from depression and a guilt delusion. For the delusion, it was recommended to start clozapine, but for the depression, the recommendation was to start a lithium addition. You explain and discuss these options. Eventually we both agreed to start with the depression protocol, before starting clozapine. We also agreed it was a mood congruent delusion. TREAT really helps to show things in this way." [C11]

In conclusion, although respondents have different opinions about the benefits and different aspects of TREAT, they all agree that the application facilitates shared decision-making. In total, five themes explain the use and evaluation of TREAT by clinicians (Table 2). In addition, all four predictors of the UTAUT model were positively evaluated by the majority of the respondents.

Table 2 Summary of results

Views on TREAT's:	TREAT experienced as promoting	TREAT experienced as limiting
1. Graphic representation	Improved representation versus ROM-letter	Successful feedback routines not in need of change
2. Treatment recommendations	Supported clinical reasoning and discussions with patients	Too generic, comprehensive or inapplicable
3. Contextual factors	Structured and complete screening routines	Time pressure and unavailable resources
4. Effects on patients	Sense of ownership and increased commitment	Overwhelming and difficult
5. Effects on shared decision-making	Facilitated shared decision-making	Clinical decisions often remained unchanged

DISCUSSION

To the best of our knowledge, this is the first qualitative study to examine the attitudes of clinicians working with a CDA in psychosis care. Clinicians were the primary focus of this study because they have to adopt TREAT for successful implementation. Clinicians reported both positive and negative experiences with the TREAT application. Two groups emerged: those who experienced TREAT as beneficial to their daily clinical practice and those who did not. Psychiatrists were divided, while nurse practitioners held the most positive attitudes. Nurse practitioners were more willing to change their normal consultation routines and use the guideline-based treatment recommendations. Age and work experience in psychosis care, did not influence the use nor evaluation of TREAT. Thematic analysis revealed five recurrent themes that provided insights into how TREAT was used and perceived.

Many respondents mentioned time pressure as a prevalent issue. TREAT did not decrease the average consultation time. This was mostly due to comprehensive coverage of topics and because clinicians had to become familiar with the application. In general the consultation time increased but at the same time more topics were discussed, oftentimes in a more efficient and collaborative way. The graphical user interface was experienced as an improvement over the existing text-based report letter provided by the routine outcome monitoring (ROM) system. For most clinicians it became easier to integrate the feedback of ROM-results into their consultations with patients. This is an important finding, as previous research has shown that CDAs that are difficult to integrate in existing care processes are not used by clinicians after the experimental introduction (4).

In contrast with the positive responses on the visual presentation of the individual ROM data, clinicians held different opinions about the guideline-based treatment recommendations. Some respondents indicated to be well aware of existing guidelines and questioned the usefulness of TREAT's recommendations for daily clinical practice. Other clinicians did use the recommendations to support their clinical reasoning and to discuss the suggested interventions with their patients. Applicability was an issue for some of the recommendations, as they were sometimes experienced as too generic, required missing resources, or had already been suggested or tried before by patients. Only some clinicians mentioned interventions or treatments that were started following treatment recommendations of TREAT. Cognitive behavioral therapy (CBT) and eye movement desensitization and reprocessing (EMDR) for example, were often recommended but in several teams unavailable due to absence of a specialized psychologist. This is in line with a regional psychosis care assessment in The Netherlands, which revealed limited availability for several guideline-based interventions (20). Unavailability of resources has to be addressed in order to successfully implement tools such as TREAT. The availability of recommended interventions is a prerequisite for the efficacy of any CDA (1,4).

Although clinicians were divided about the benefits of the treatment recommendations, they all agreed that TREAT contributed to more shared decision-making (SDM). This is an important finding, as SDM in psychosis care is considered desirable, yet difficult to achieve (21). Making shared decisions can increase treatment adherence and bolster empowerment of people with psychotic

illness (22,23). SDM tries to change the traditional power asymmetry between patients and clinicians (24). The treatment recommendations and the graphic representation of the ROM-results can contribute to SDM by strengthening the exchange of information and the decisional position of patients. Some clinicians noticed more commitment from their patients during consultations and a stronger sense of ownership of their ROM-data, when using TREAT. It has to be noted that not all patients responded equally well to the application according to clinicians, with some even having negative responses. Concerns were also expressed about TREAT in relation to personal recovery. Some clinicians stated that the focus might still be too much on the symptoms, burdens and problems, instead of strengths and the opportunities for support and treatment. However, increasing SDM, autonomy and a sense of ownership over the data during consultations, makes TREAT compatible with personal recovery-oriented care (25).

We also utilized the Unified Theory of Acceptance and Use of Technology (UTAUT) as presented in Figure 1 to summarize our findings. Most interviewed clinicians perceived TREAT as beneficial, user-friendly, easy to use and experienced minimal burden. Therefore, the predictive factors of performance and effort expectancy were generally positively evaluated. There was little social influence because clinicians participated by their own choice. They were often the only ones in their team to join the study and experienced no external pressures to work with TREAT. All respondents agreed that the facilitating conditions for implementation of the application into the existing technical infrastructure and care processes were met. Although no statistical generalizations can be made from these findings, all predictive factors of the UTAUT model were positively evaluated by clinicians.

Strengths and limitations

Some limitations of this study need to be addressed. One main limitation is a possible selection bias. We emphasized the importance of clinicians with skeptical attitudes towards CDAs in general and TREAT in particular while recruiting participants for this study. However, an oversampling of clinicians with a more favorable attitude cannot be ruled out. Furthermore, we only interviewed clinicians that worked with the application on at least three different occasions. We were interested in their opinions because they had enough experience to evaluate TREAT and help us understand the way in which the application was used.

Clinicians that worked with TREAT only once or twice filled out a short anonymous questionnaire to assess what complications they faced in completing the intended four measurements. The most common reasons were clinicians discontinuing their work within the team or organization during the trial, consulting insufficient patients that met the inclusion criteria and logistical issues with planning and carrying out measurements. Although not specifically mentioned in the anonymous questionnaire, we cannot rule out the possibility that some clinicians who were not included in this study had stopped using TREAT after trying it once or twice because of a perceived lack of benefit. The main strength of this study is that we reached data saturation with a diverse group of respondents. Both male and female psychiatrists and nurse practitioners from different ages and with varying years of experience in psychosis care were interviewed. No psychologist participated because they are underrepresented in psychosis care and are less involved with the annual treatment plan evaluations. Clinicians were recruited from teams in four different institutions from both urban and rural areas. The diversity of respondents supports the transferability of our results.

Future research and improvements

This study provides insights into the use and evaluation of TREAT by clinicians. Some questions about the effects of TREAT on daily clinical practice remain unanswered. Furthermore, several improvements were suggested for future use. Nearly all clinicians perceived more SDM when working with TREAT. This requires additional quantitative assessment. Furthermore, it is important to investigate the perspectives of patients because we do not know how they experience CDAs in general and in psychosis care in particular. Our current trial measures patients' decisional conflict to assess whether TREAT can facilitate SDM during consultations. Patients' ratings of these consultations are also included. According to clinicians, not all patients responded equally well to TREAT, because the focus is mainly on problems and less on the improvements in treatment. For future development, clinicians often recommended incorporating ROM-data from previous years to visualize positive health trends of patients in treatment. They also suggested increasing the interactivity of TREAT. For example, by asking patients to prioritize areas of interest or by adding small scripts with relevant questions for identified problems. Furthermore, multiple clinicians requested a

similar application for other mental illnesses such as depressive, borderline or bipolar disorders. It is worthwhile to explore new ways of collecting data, for example with the experienced sampling method or by utilizing smart devices (26). Moreover, newly developed models and guidelines for the deployment of machine learning and artificial intelligence in psychiatry, could improve new CDAs (27). A continuously growing body of evidence could provide future designers with guidelines for development and implementation of these tools.

Conclusions

This article describes the use and evaluation by clinicians of a computerized clinical decision aid in the treatment of people with psychotic disorders. Most clinicians experienced TREAT as easy to use and beneficial to their consultations. The structured visual representation of ROM-results was generally well-appreciated and provided cues to discuss treatment planning with patients. The guideline based treatment recommendations supported clinical reasoning but did not seem to change most treatment decisions. The delivery and applicability of the recommendations and the availability of the recommended interventions need improvement for successful implementation. Most patients seemed to appreciate TREAT but not all, according to clinicians. The observation that TREAT facilitates shared decision-making is promising but requires further quantitative assessment. Future research should also focus on patients' perspectives to investigate which patients respond best to CDAs in psychosis care. All four predictors of the Unified Theory of Acceptance and Use of Technology were positively evaluated by the majority of clinicians. The full impact of TREAT on daily clinical practice still has to be assessed in the ongoing clinical trial and in future research.

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Appendix 1. The interview guide used for the in-depth interviews with clinicians

Introduction

Welcome and thank you for participating in this interview. This interview is part of the TREAT project. With this project, we would like to investigate the effects of TREAT on clinical encounters.

As part of a qualitative study, we conduct this interview. During this interview, it is important to be aware that participation is voluntary. Feel free to end your participation and leave at any time. However, we appreciate all opinions and hope you will share these with us.

Everything discussed in this interview is confidential and will be used for scientific purposes only. There are no good or bad answers, so feel free to speak your mind.

This entire conversation will be recorded. All recordings will be safely stored and will only be available to the research team in the context of scientific research. The information will be summarized and untraceable to individual participants. In case of specific quotations, the names of the speaker will be modified so they are untraceable to individual participants.

Topics:

Wat is your general impression of TREAT?

- *Which aspects work well and which ones work less well?*
- *Wat would you like to change or improve about TREAT?*
- *Wat is your opinion on the design and accessibility through the electronic patient file of TREAT?*

In what way did you use TREAT?

- *To what extent did you find TREAT user-friendly?*
- *To what extent do you feel obligated to work with TREAT?*
- *To what extent do you feel others should work with TREAT?*

What are the effects of TREAT on your clinical encounters?

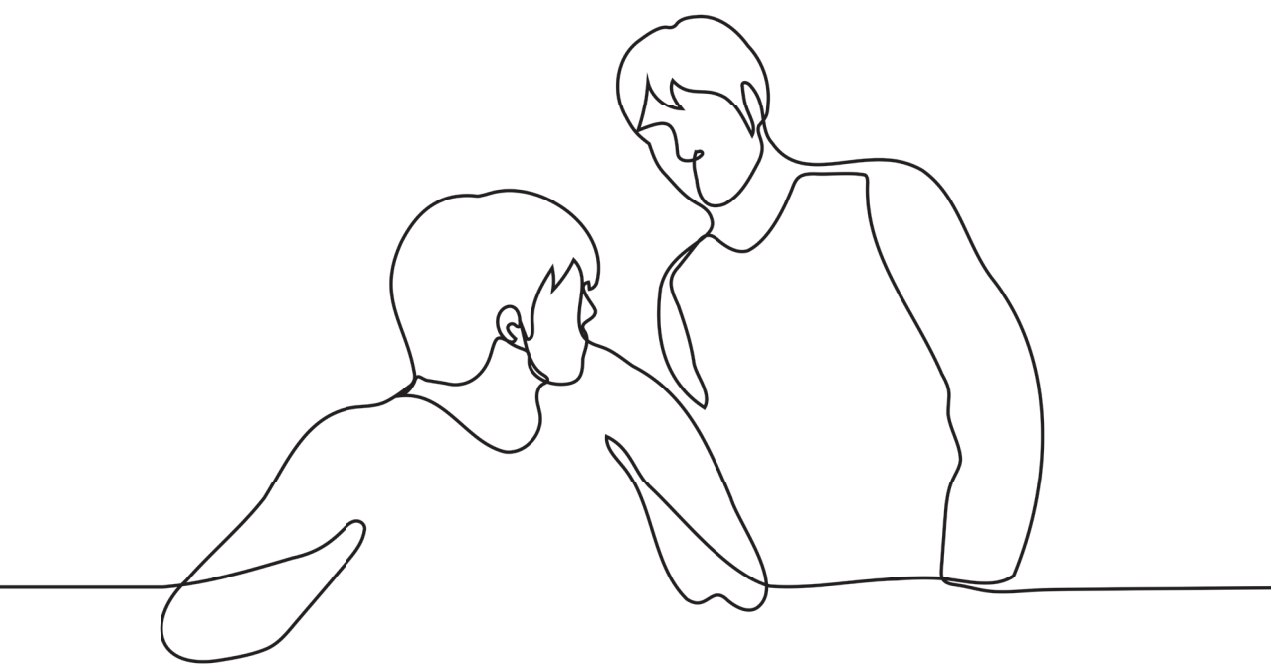
- *In which way does TREAT facilitate your work?*
- *What is the effect of TREAT duration of the clinical encounters?*
- *What is the effect of TREAT on the use of ROM-data?*
- *What is the effect of TREAT on shared decision-making?*
- *What is the effect of TREAT on patient contact?*

What is your opinion about the treatment recommendations of TREAT?

- *In which way did you use the treatments recommendations?*
- *To what extent are treatments or interventions available?*
- *Which non evidence-based treatments or interventions do you offer?*

Did you feel you were able to express your opinion about TREAT properly?

Is there something else you would like to discuss which has not yet been discussed?



Chapter 6

The effects of a computerized clinical decision aid on shared decision-making in the treatment of psychotic disorders

Lukas O. Roebroek, Jozanneke Bruins, Albert Boonstra, Philippe A.E.G. Delespaul,
Stynke Castelein

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ABSTRACT

Background: People with psychotic disorders can experience a lack of active involvement in their decisional process. Clinical decision aids are shared decision-making tools which are currently rarely used in mental healthcare. We examined the effects of Treatment E-Assist (TREAT), a computerized clinical decision aid in psychosis care, on shared decision-making and satisfaction with consultations as assessed by patients.

Methods: A total of 187 patients with a psychotic disorder participated. They received either treatment as usual in the first phase (TAU1), TREAT in the second phase or treatment as usual in the third phase of the trial (TAU2). Scores on the Decisional Conflict Scale were used as primary outcome measure for shared decision-making. Patient satisfaction ratings of consultations were measured with the Session Rating Scale as secondary outcomes.

Results: A linear mixed model analysis found high levels of shared decision-making but no significant effects between TAU 1 ($\beta = -0.54$, $SE = 2.01$, $p = 0.80$) and TAU 2 ($\beta = -1.66$, $SE = 2.63$, $p = 0.53$) compared to the TREAT condition. High patient rated satisfaction with the consultations was found with no significant differences between TAU 1 ($\beta = 1.48$, $SE = 1.14$, $p = 0.20$) and TAU 2 ($\beta = 2.26$, $SE = 1.33$, $p = 0.09$) compared to the TREAT condition.

Conclusion: We expected TREAT to enhance shared decision-making without decreasing the overall satisfaction with the consultations. However, no significant differences on shared decision-making or satisfaction with consultations were found. Our findings suggest decision aids such as TREAT are safe to implement in psychosis care, but more research is needed to fully understand their effects on the decisional process.

BACKGROUND

Treatment of psychotic disorders

Psychotic disorders occur in approximately three to four percent of the Western population (1,2). They are often characterized by severe and persistent positive symptoms (such as hallucinations, delusions and incoherent thoughts) and negative symptoms (such as flat affect, loss of initiative and social withdrawal) (3). Apart from psychiatric symptoms, people with psychotic disorders are usually faced with other challenges, such as somatic issues, loneliness, stigmatizing and difficulty to participate in work or study. This all contributes to a lower quality of life (4-6) and a severely reduced life expectancy (7). Some symptoms, somatic problems and psychosocial issues remain unresolved and are considered care needs that persist over time (8-11). Identifying these needs and subsequently indicating adequate treatment is important, but challenging, requiring a long-term iterative process between patient and clinician. Routine outcome monitoring (ROM), described as the use of standard instruments to systematically assess the health and wellbeing of patients (12), can be helpful in identifying care needs of patients. The systematic feedback of ROM results improves the treatment process in mental healthcare (13). Ideally, ROM provides input for shared decision-making (SDM) about patients' existing issues and the course of treatment but the integration into daily clinical practice of psychosis care can be challenging (14).

Shared decision-making

In recent years there has been a gradual transition in mental healthcare from a paternalistic model, in which clinicians hold most of the knowledge and decisional power, towards a more patient-centered informed choice model of decision-making (15). SDM is a process intended to facilitate this transition by strengthening the exchange of information and the decisional position of patients with a severe mental illness (16). Many definitions of SDM exist but a systematic review identified some of the most consistent aspects: present treatment options to the patient, clarify decisions to be made, discuss benefits and risks of treatment options, incorporate patient preferences and values, make recommendations and decide on treatment course (17). Mental health professionals acknowledge the importance of SDM yet it is not regular practice in the treatment of severe

mental illness (16). In a UK survey (n = 5028) for example nearly two-third of the people with psychotic illnesses did not feel actively involved in the decisional process regarding their own treatment (18). This highlights the importance for continued efforts to increase SDM in mental healthcare (19), for which different types of interventions are available (20). A concrete example are clinical decision aids (CDAs), which gain popularity and facilitate aspects of SDM in various medical disciplines (20,21).

Decision aids and Treatment E-Assist

CDAs are tools such as evidence-based booklets, websites or computer applications, supporting patients and clinicians with healthcare decisions (22). These tools improve the decisional position of patients by increasing their knowledge about decisions that need to be made and available treatment options. (22). A growing body of evidence shows the efficacy of CDAs (21), yet research on these tools in the treatment of severe mental illness is limited (23). In psychosis care, lower re-hospitalizations rates and reduced clinical symptoms were demonstrated when a CDA was used (24,25). Concerns exist about potential negative effects of CDAs, for example by depersonalizing interactions during clinical encounters (26). Furthermore, computerized CDAs might require high technological proficiency to use, potentially disrupting existing workflows during consultations (27). Drawing on these findings, we developed Treatment E-Assist (TREAT). TREAT is a pragmatic and user-friendly, computer based CDA for the treatment of people with psychotic disorders. To the best of our knowledge, TREAT is the first CDA in mental healthcare combining ROM results with guidelines and standards of care to generate personalized treatment advice for individual patients. The developmental process and pilot results are published elsewhere (28). TREAT highlights patients' care needs during treatment plan consultations based on their latest ROM screening and provides relevant treatment suggestions for these needs based on the Dutch multidisciplinary guideline for schizophrenia and the care standard for psychosis (29,30). We expect TREAT to improve all aspects of SDM between patient and clinician by presenting treatment decisions, increasing the exchange of information and knowledge about guideline-recommended treatment options as well as opening the discussion about these options and patients' personal preferences without decreasing their overall satisfaction with the consultations.

Research aim

This first aim of this study is to investigate whether patients with psychotic disorders working with a clinical decision aid (TREAT) experience more shared decision-making than patients receiving treatment as usual. Secondly, we examine the effects of this CDA (TREAT) on the overall satisfaction of these patients with their consultations.

METHODS

Setting and participants

From the 33 clinicians originally contracted, a total of 27 clinicians actually participated in the trial and worked with TREAT. They were recruited from four mental healthcare institutions in the Northern-Netherlands. All clinicians worked in flexible assertive community treatment (FACT) teams (31), as psychiatrists (n=13), psychologists (n=3) or nurse-practitioners (n=11). Clinicians received a brief training on how to use TREAT. All patients of the participating clinicians which were successively scheduled for treatment plan consultations were asked to participate in this study by their secretariat. Patients had to be adults with a DSM-5 diagnosis of a psychotic disorder (295.90, 295.40, 295.70, 297.1, 298.8 or 298.9) (32). They needed to complete their most recent Pharmacotherapy Monitoring and Outcome Survey (PHAMOUS) screening (33), be fluent in Dutch and able to give an informed consent. Clinicians were reminded by the research team about upcoming measurements after which the questionnaires were provided by mail. Participation was voluntary and all patients signed an informed consent. The Medical Ethical Committee of the University Medical Center Groningen (UMCG) approved this study (Research registration number 201700763, date January 9, 2018). Our procedures were in accordance with local legislation and the Declaration of Helsinki. Data was collected from April 2018 until March 2020 (aborted 7 weeks sooner than planned due to the COVID-19 pandemic).

Trial design and sample size

An ABC study design with three phases lasting 8 months (the last phase was seven weeks shorter due to the COVID-19 pandemic) was used. In the A phase clinicians provided treatment as usual (TAU) in their treatment plan consultations. In the B

phase the clinicians used TREAT in their treatment plan consultations. TREAT was only accessible in this phase and intervention fidelity was checked by examining whether TREAT reports had been generated for all included patients. In the C phase, the clinicians provided only TAU again. Clinicians participated with a minimum of 1 and a maximum of 4 consultations during each phase (phase 1: M=3.22, phase 2: M=2.66, phase 3: M=2.25). Each consultation took place with different patients. Studies from a review by Stacey et al. (21), in which CDAs were tested against TAU with the DCS as outcome, were used to calculate the approximate sample size of n=81 patients per trial phase (n=243 patients in total).

Outcome measures

Decisional conflict (DC) provides insight into the quality of the decisional process and decisional outcomes from a patient perspective (34,35). DC is a useful construct for evaluating the application of SDM in daily clinical practice (21,36,37). Therefore, we used DC measured with the Decisional Conflict Scale (DCS) (38), as the primary outcome to measure SDM. The DCS consists of 16 items on a 5-point Likert scale, ranging from strongly agree (0 points) to strongly disagree (4 points). The sum of all items was divided by 16 and multiplied by 25. Resulting scores range from 0 to 100 with higher scores indicating more decisional conflict. Scores below 25 indicate an absence of decisional conflict and thus complete SDM, whereas scores above 37,5 indicate an uncomfortable decisional process and thus suboptimal SDM (35). The DCS consist of five subscales, reflecting important aspects of SDM: 1) feeling informed about the treatment options, 2) being clear about ones values regarding the treatment options, 3) feeling supported in decision-making, 4) feeling uncertainty about the decision and 5) feelings about the quality of the decision (38). Scores for all subscales were recalculated to range from 0 to 100. The DCS has test-retest correlations and Cronbach alpha coefficients ≥ 0.78 (38). A validated Dutch translation of the DCS was used (37).

Patient satisfaction ratings of the consultations were used as a secondary outcome, measured by the Session Rating Scale (SRS) (39). The SRS is a Visual Analog Scale (VAS) which measures satisfaction with clinical encounters on four dimensions: 1) relationship, 2) goals and topics, 3) approach and method and 4) overall satisfaction. The total score of these 4 items ranges from 0 to 40 points. Higher scores indicate a more positive rating of the session. A validated Dutch

translation of the SRS was used with a Cronbach alpha of 0.89 and test-retest correlation of 0.57 (40). Patients filled in paper versions of the DCS and SRS directly after their consultations and returned the questionnaires in a closed envelope, ensuring anonymity.

Analysis

Demographic characteristics between conditions were tested with independent-samples t-tests (age and duration of illness) or Pearson's chi-square (χ^2) test (gender and diagnosis). The effects of TREAT on SDM were analyzed with a multilevel analysis comparing both TAU conditions to the TREAT condition. Prior to the analysis, the intraclass correlations (ICC) were calculated for the DCS and SRS to assess the ratio of within-groups variance to between group-variance components as an indication for clustering of the data within clinicians (41). The ICCs were <0.05 for both the DCS and SRS, indicating low levels of clustering within clinicians. A two-level linear mixed model was built for all outcome measures. Clinicians were modeled as level 2 and patients were modeled as level 1. To account for the ABC design, both TAU 1 (1, 0, 0) and TAU 2 (0, 0, 1) were dummy coded and added to the model as a fixed effects. In total 3% of the data on the DCS and SRS was missing at random. Random effects for the intercepts were used with variance components as covariance structure (42). Multiple imputations with predictive mean matching were used to impute missing data, adding to a total of five imputed datasets which were combined using Rubin's rule (43). The pooled effects were compared with the original dataset to evaluate the impact of the imputation. All statistical analyses were tested against a 0.05 significance level and performed using the Statistical Package of the Social Sciences (SPSS), version 27 (44).

RESULTS

Demographics

We included 187 patients in this study, of which $n=87$ in the first TAU condition, $n=64$ in the TREAT condition and $n=36$ in the second TAU condition (see table 1). The unequal distribution can be attributed to the drop-out of participating clinicians (3 dropouts for the TREAT condition and 7 for the second TAU condition). In total 17 clinicians completed the trial. Drop-outs were due to job changes or a

lack of eligible patients in their caseloads. TREAT reports were generated for all 64 patients in the TREAT condition, indicating appropriate intervention fidelity. Our sample contained slightly more men (69.9% vs 65.8%), were slightly older (49.2 vs 45.1) and had a longer average duration of illness (23.3 vs 17.6 years) compared to the PHAMOUS population (31,33). No significant differences were found in age, gender, duration of illness or diagnosis between conditions except for the percentage of people with a schizoaffective disorders (see table 1).

Table 1. Demographics and clinical characteristics of patients in TREAT trial (n=187)

Demographics	TAU 1 Mean	TREAT Mean	TAU 2 Mean	p-value / χ^2
Age, years (SD)	48.1 (9.2)	49.9 (10.2)	52.3 (10.2)	0.13
Gender male, % (n)	65.0 (52)	74.0 (37)	75.0 (21)	0.44
Illness duration years (SD)	22.4 (10.3)	22.2 (11.8)	27.5 (11.6)	0.11
Diagnosis % (n)	TAU 1 Mean	TREAT Mean	TAU 2 Mean	χ^2
Schizophrenia	46.0 (40)	42.2 (27)	55.6 (20)	0.08
Schizoaffective disorder*	19.5 (17)*	12.5 (8)	0 (0)*	0.03
Substance induced	10.3 (9)	14.1 (9)	8.3 (3)	0.51
Definitive diagnosis missing	9.1 (6)	15.3 (10)	14.3 (5)	0.58
Schizophreniform disorder	2.3 (2)	0 (0)	2.8 (1)	0.45
Delusional disorder	1.2 (1)	1.6 (1)	2.8 (1)	0.73
Definitive diagnosis missing	12.6 (11)	12.5 (8)	13.9 (5)	0.91

* significant difference between two conditions

SD, standard deviation

Shared decision-making

The total mean scores on the DCS indicated high levels of SDM (see table 2) but did not significantly differ between both TAU 1 ($\beta = -0.54$, SE = 2.01, $p = 0.80$) and TAU 2 ($\beta = -1.66$, SE = 2.63, $p = 0.53$) compared to the TREAT condition. Furthermore, mean scores on the different subscales of the DCS were also not significantly different between both TAU conditions and the TREAT condition (see table 2).

Session ratings

There were no statistically significant differences in total mean scores on the SRS between both TAU 1 ($\beta = 1.48$, $SE = 1.14$, $p = 0.20$) and TAU 2 ($\beta = 2.26$, $SE = 1.33$, $p = 0.09$) compared to the TREAT condition. Nor were there significant differences between both TAU conditions compared to the TREAT condition on the individual items of the SRS (see table 2).

Table 2. Mean scores, betas, confidence intervals and p-values decisional conflict scale and session rating scale

	TAU 1 Mean (SD)	TREAT Mean (SD)	b (95% CI)	p-value
<i>DCS Total</i>	27.6 (11.3)	28.2 (14.9)	-0.54 (-4.59, 3.52)	0.80
<i>Informed Values</i>	30.9 (15.3)	29.1 (16.7)	1.74 (-3.62, 7.10)	0.52
<i>Support</i>	27.4 (14.6)	28.1 (16.7)	-0.69 (-5.44, 4.06)	0.78
<i>Uncertainty</i>	24.0 (14.3)	24.3 (16.0)	-0.49 (-5.19, 4.22)	0.84
Quality	30.4 (16.4)	32.1 (19.7)	-1.71 (-7.27, 3.85)	0.55
<i>SRS Total</i>	26.1 (12.9)	27.5 (17.4)	-1.45 (-5.93, 3.03)	0.53
<i>Relationship</i>	32.4 (5.5)	31.1 (6.9)	1.48 (-0.77, 3.72)	0.20
<i>Goals & topics</i>	7.8 (1.7)	7.5 (2.2)	0.34 (-0.40, 1.07)	0.37
<i>Approach & method</i>	8.0 (1.7)	7.6 (2.0)	0.41 (-0.22, 1.04)	0.20
<i>Overall</i>	8.2 (1.5)	7.8 (2.1)	0.45 (-0.14, 1.04)	0.14
	8.3 (1.6)	8.0 (1.9)	0.29 (-0.29, 0.88)	0.33
	TAU 2 Mean (SD)	TREAT Mean (SD)	b (95% CI)	p-value
DCS Total	26.5 (9.4)	28.2 (14.9)	-1.66 (-6.81, 3.48)	0.53
<i>Informed Values</i>	29.5 (16.6)	29.1 (16.7)	0.41 (-6.41, 7.23)	0.91
<i>Support</i>	28.1 (10.9)	28.1 (16.7)	-0.05 (-6.18, 6.08)	0.99
<i>Uncertainty</i>	23.2 (13.6)	24.3 (16.0)	-1.15 (-7.47, 5.17)	0.72
<i>Quality</i>	30.8 (15.8)	32.1 (19.7)	-1.27 (-8.33, 5.78)	0.72
SRS Total	22.3 (11.9)	27.5 (17.4)	-5.24 (-11.04, 0.56)	0.08
<i>Relationship</i>	33.3 (5.7)	31.0 (6.9)	2.26 (-0.34, 4.86)	0.09
<i>Goals & topics</i>	8.2 (1.7)	7.5 (2.2)	0.66 (-0.07, 1.38)	0.08
	8.3 (1.6)	7.7 (2.0)	0.68 (-0.12, 1.48)	0.10

<i>Approach & method</i>	8.3 (1.7)	7.8 (2.1)	0.55 (-0.24, 1.33)	0.17
<i>Overall</i>	8.5 (1.9)	8.0 (1.9)	0.47 (-0.26, 1.19)	0.21

DCS = Decisional Conflict Scale; SRS = Session Rating Scale

* Range DCS Total and subscales = 0 – 100

* Range SRS Total = 0 – 40

* Range SRS subscales = 0 – 10

The original data and pooled data were compared to test the impact of multiple imputation on the outcomes (Supportive Information S2). Deltas between the pooled effects and the effects of the original dataset across both models varied between $\beta = .35$ and $\beta = .40$ on the DCS and $\beta = .08$ and $\beta = .03$ on the SRS, indicating adequate imputation.

DISCUSSION

The first aim of this study was to investigate the effects of the clinical decision aid (CDA) Treatment E-Assist (TREAT) on the level of shared decision-making (SDM) in the treatment experienced by people with psychotic disorders. No significant differences in SDM between both TAU conditions and the TREAT condition were found. This lack of measurable difference in SDM could be explained by the so-called ceiling effect. When score distributions of a certain variable tend to be skewed, as happens with ceiling, a regression could lead to inaccurate predictions (45). More than half of all patients scored 25 or lower on the DCS indicating absence of decisional conflict during consultations. Average scores on the DCS and its subscales were well below the threshold of 37.5 for indicating an uncomfortable decisional process. Therefore, potentially facilitating effects of TREAT on aspects of SDM are harder to detect. These high levels of SDM were unexpected and different from another recent study on Dutch patients in specialized mental healthcare (17% psychosis), in which an uncomfortable decisional process was reported with mean DCS scores of 38.8 (37). These differences might stem from the relatively long duration of illness in our sample (mean: 23 years), likely meaning that most participants are very knowledgeable about their illness. They mostly receive long-term care, focused on long-term disease management. These treatment decisions tend to be less acute compared to first episodes of psychosis

or other medical disciplines, such as oncology or cardiology. CDAs in those medical fields have shown to increase aspects of SDM, but those treatment decisions were surrounded by considerably more decisional conflict at baseline compared to our sample (46-48). Notably, our results did not confirm earlier findings from a qualitative assessment in which the same clinicians perceived more SDM while using TREAT because of a perceived increase in the exchange of information and discussion about treatment options (14). This exchange of information aspect of SDM correlates to the informed subscale of the DCS, yet no significant differences were observed on this subscale. Another aspect of SDM is the incorporation of patients' personal preferences and values in the decisional process, but the non-significant differences on the value clarity subscale do not indicate improvements on this aspect either. In sum, it would be valuable to repeat this experiment in a sample of patients and clinicians who experience more decisional conflict.

The second aim of this study was to examine the effects of TREAT on the overall satisfaction of patients with their consultations. No statistically significant differences were found and satisfaction was high in all conditions, indicating that TREAT did not change patients' perceived quality of the clinical encounters. Existing concerns about potential negative effects of CDAs on the therapeutic relationship in mental healthcare settings, potentially depersonalizing consultations, were not confirmed by our findings. Overall, these findings suggest that computer based CDAs such as TREAT are safe to implement in psychosis care from a patients' point of view but so far no indication was found for its use in increasing SDM.

Strengths & Limitations

To the best of our knowledge, this is the first study in psychosis care evaluating the effects of a CDA during clinical encounters across multiple mental healthcare institutions. Considering the broad inclusion criteria for participants, this study has high ecological validity.

Randomization was impossible as TREAT can only be switched on or off in the electronic patient record for all participating clinicians. We opted for an ABC design to ensure that clinicians had no prior exposure to TREAT. A strength of this design is that participating clinicians provided care in both conditions of the trial. This limits the variance on a clinician level, as was shown by their low intra

class correlations. The second TAU mitigated potential time effects and served as a control-comparison for the first TAU phase, since conditions may change over time, for example due to changes in institutional policies or implementation of new guidelines and treatments. The COVID-19 pandemic caused a potential time effect hence the last TAU phase was stopped earlier than intended. This resulted in a somewhat underpowered study but with almost no missing data. At the same time we were able to study a potential carryover effect from the TREAT intervention.

A TREAT report was created for every patient in the TREAT condition, indicating that all clinicians attempted to use the application in their consultations. However, alternative indicators of intervention fidelity were absent. In other words, we do not fully understand how TREAT was utilized in this trial to facilitate aspects of SDM. Much of the content of clinical encounters in mental health remains a black box, making intervention fidelity and implementation of CDAs in daily clinical practice a tenuous endeavor (49).

A final limitation of this study is that some participants had difficulty in filling in the DCS, because the formulation of the questions was sometimes perceived as complicated.

Future research

Different SDM interventions exist in mental healthcare, such as training clinicians in problem definition and agreement, or interventions aimed at patients for enhancing involvement and autonomy in the decisional process (20). SDM interventions in the form of CDAs are still scarce in mental healthcare (23) and their implementation in regular clinical practice can be challenging (50). Currently available tools are generally used outside of clinical encounters (21), for example in the form of evidence-based booklets or online educational tools which patients use to prepare themselves for upcoming consultations (23). TREAT is unique in mental healthcare because it is used collaboratively during clinical encounters, aiming to shift a potential knowledge and decisional asymmetry between patient and clinician. Not all patients responded well to TREAT as some found it confrontational or complicated (14). Moreover, some patients in psychosis care experience reduced decisional ability due to their illness (51), limiting the potential

benefits of a CDA. Future research should examine which patients benefit most from CDAs such as TREAT. Alternative patient outcomes such as empowerment or autonomy are also worth investigating in relation to CDAs (52). The systemic feedback of ROM results has the potential to improve clinician performance (13). TREATs feedback and treatment recommendations are used collaboratively by patient and clinician, therefore a second part of this trial will investigate its effects on clinical decision-making.

Conclusions

This study investigated the effects of a clinical decision aid named TREAT on shared decision-making (SDM) during treatment plan consultations in psychosis care. We expected TREAT would improve SDM by increasing the exchange of information and by aligning decisions with patient's personal preferences, but no differences in SDM were detected between TREAT and TAU. In contrast to other patient populations in mental healthcare, participants experienced minimal decisional conflict. SDM and satisfaction rates were high in both conditions suggesting that TREAT did not depersonalize clinical encounters, disrupt existing workflows or decrease the quality of consultations. These findings suggests that decision aids such as TREAT can be safely implemented in psychosis care, but so far have not demonstrated to increase SDM. A second part of this trial will investigate if TREAT can benefit patients by improving decisional process in other ways during consultations.

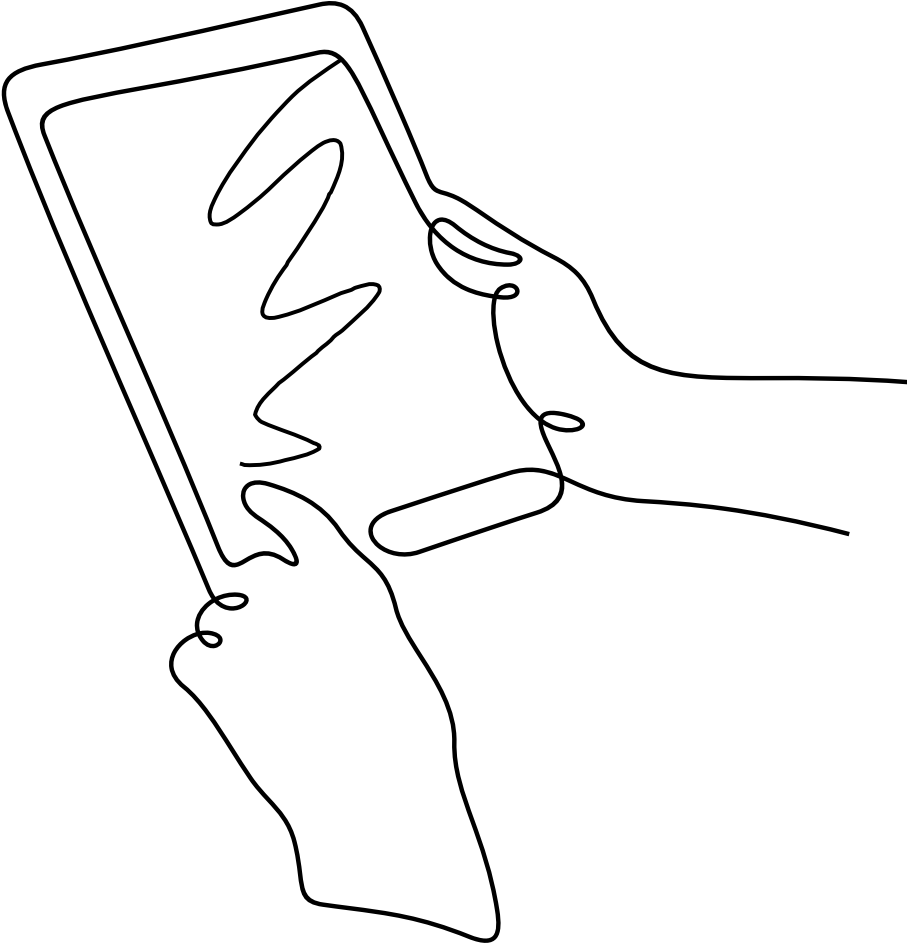
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Chapter 7

The effects of a computerized clinical decision aid on clinical decision-making and guideline implementation in psychosis care

Lukas O. Roebroek, Jozanneke Bruins, Albert Boonstra, Wim Veling, Frederike Jörg, Esther Sportel, Philippe A.E.G. Delespaul, Stynke Castelein

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ABSTRACT

Background: Clinicians in mental healthcare have few objective tools to identify and analyse their patient's care needs. Clinical decision aids are tools that can support this process. This study examines whether 1) clinicians working with a clinical decision aid (TREAT) discuss more of their patient's care needs compared to usual treatment, and 2) agree on more evidence-based treatment decisions.

Methods: Clinicians participated in consultations (n=166) with patients diagnosed with psychotic disorders from four Dutch mental healthcare institutions (research registration number 201700763). Primary outcomes were measured with the modified Clinical Decision-making in Routine Care questionnaire and combined with psychiatric, physical and social wellbeing related care needs. A multilevel analysis compared discussed care needs and evidence-based treatment decisions between treatment as usual (TAU) before, TAU after and the TREAT condition.

Results: First, a significant increase in discussed care needs for TREAT compared to both TAU conditions ($\beta = 20.2$, $SE = 5.2$, $p = 0.00$ and $\beta = 15.8$, $SE = 5.4$, $p = 0.01$) was found. Next, a significant increase in evidence-based treatments decisions for care needs was observed for TREAT compared to both TAU conditions ($\beta = 16.7$, $SE = 4.8$, $p = 0.00$ and $\beta = 16.0$, $SE = 5.1$, $p = 0.01$).

Conclusions: TREAT improved the discussion about physical health issues and social wellbeing related topics. It also increased evidence-based treatment decisions for care needs which are sometimes overlooked and difficult to treat. Our findings suggest that TREAT makes sense of ROM data and improves guideline-informed care.

INTRODUCTION

Clinical decision-making in mental healthcare

Clinical decision-making is a process in which clinicians identify the symptoms, needs and challenges of their patients and ideally integrate them with available medical evidence to reach an agreement on the most beneficial treatment (1). Clinical decisions in mental healthcare are often characterized by incomplete and conflicting information, sometimes leaving outcomes prone to bias or personal preferences of clinicians (2,3). Compared to other medical disciplines, clinicians in mental healthcare generally rely on observations and self-reports from their patients. It can be complicated to objectify these observed and reported symptoms using measurement instruments. Consequently, the process of clinical advice in mental healthcare is a complex combination of diagnostic skills and experience, while implications are hampered by the pragmatics of time constraints and the availability of resources (4). Mental health in general and psychosis care particularly, is comprehensive. Psychiatric symptoms, physical health issues, and challenges related to social wellbeing can remain unresolved and are therefore considered care needs that persist over time (5). Treatment decisions ideally apply to psychiatric symptoms, somatic risk factors and issues related to social wellbeing (6,7). Routine outcome monitoring (ROM) provides clinicians with information to identify these comprehensive care needs. Routine outcome monitoring (ROM) uses standard validated instruments to systematically assess patient's health and well-being (8). It can be challenging to integrate ROM results into daily clinical practice in mental healthcare. For example, in one study, only half of all clinicians actively used ROM results for feedback during consultations (9). In addition, certain needs identified by ROM, can remain undiscussed in the decisional process during consultations (10). Some attempts have been made to study the content of clinical encounters in psychosis care (11,12). Psychiatric symptoms and medication are among the most frequently discussed topics: pharmacological treatments are about three times more likely to be discussed and initiated than non-pharmacological treatments (11,12). Psychosocial wellbeing (e.g. daytime activities, work, or social relations) are also frequently discussed. However, making treatment decisions in these domains is more challenging to implement and generally requires more time and effort (11,12). Also, physical health issues such as hypertension or anticholinergic side effects often remain unnoticed or undiscussed and, therefore, untreated, resulting in an increasing burden over time (5-7,13).

Clinical decision aids and Treatment E-Assist

Clinical decision aids (CDAs) are tools that support clinicians and patients when making healthcare decisions (14). They help address issues and needs during clinical encounters which might otherwise go unnoticed or remain undiscussed. Because there is a gap between guideline-informed care and actual clinical decision-making, CDAs can improve guideline implementation (15). The use of CDAs in the treatment of severe mental illness is currently limited (16). Moreover, much of how clinicians and patients use CDAs during these encounters is unknown, as trials are often designed as a black box (17), not taking into account the content and process of the treatment plan consultations (18). The Treatment E-Assist (TREAT) application was developed to improve the use of ROM in daily clinical practice, to identify care needs, and to provide guideline implementation. This computerized clinical decision aid supports the decision-making process in the treatment of people with psychotic disorders. To our knowledge, TREAT is the first CDA to combine ROM results with official treatment guidelines and standards of care to provide personalized treatment advice for individuals in mental healthcare. The developmental process, pilot results, and qualitative assessment are published elsewhere (19,20). TREAT uniquely displays the patients' identified care needs and evidence-based treatment recommendations. It can be used during clinical encounters in which treatment plans are drafted. We expect TREAT to improve and increase the number of identified care needs discussed during consultations. Furthermore, we expect TREAT to assist guideline implementation, resulting in a greater number of evidence-based treatment decisions.

Research aim

The aim of this study is to examine whether 1) clinicians working with a clinical decision aid (TREAT) discuss more of their patient's care needs compared to usual treatment, and 2) the use of this CDA (TREAT) results in a greater number of evidence-based treatment decisions.

METHODS

Setting, design and sample

Clinicians (n=33) were recruited from four mental healthcare institutions in the Northern Netherlands, 27 actually participated. Clinicians worked as psychiatrists (n=13), psychologists (n=3) or nurse practitioners (n=11) in Flexible Assertive Community Treatment (FACT) teams (21). Clinicians participated during treatment plan consultations with their patients. Clinicians received a brief training on how to use TREAT. Meetings were scheduled by the secretariat of participating teams. The patients had to be adults with a DSM-5 diagnosis of a psychotic disorder (295.90, 295.40, 295.70, 297.1, 298.8, or 298.9) (22), who recently completed the local ROM screening called the Pharmacotherapy Monitoring and Outcome Survey (PHAMOUS) (23). Written informed consent was obtained from all patients. Clinicians were reminded by the research team about upcoming scheduled assessments, after which a digital questionnaire was provided by e-mail. An ABC study design was used for this study. In the first phase (A), all clinicians provided treatment as usual (TAU), in the second phase (B), the same clinicians worked with TREAT, in the third phase (C) all clinicians again provided TAU. Intervention fidelity was examined by checking if TREAT reports were generated for all clinical encounters in the TREAT phase. Included clinicians had to participate with a minimum of 1 and a maximum of 4 consultations (phase 1: M=2.4, phase 2: M=2.7, phase 3: M=2.1) in each phase. All treatment plan consultations featured different patients. Based on a review by Stacey et al. (24), in which CDAs were tested against TAU, we calculated the power and concluded to need an approximate sample size of n=81 consultations per trial phase (n=243 consultations in total). The Medical Ethical Committee of the University Medical Center Groningen (UMCG) approved this study (Research registration number 201700763, date January 9, 2018). The procedures of this research protocol were in accordance with local legislation and ethical standards as well as the Declaration of Helsinki. Data was collected from April 2018 until March 2020 (aborted by seven weeks due to the COVID-19 pandemic).

Care need outcomes

The outcomes of the PHAMOUS screening from patients that participated in the consultations of this study were used to identify their care needs. We used the TREAT algorithms to calculate 23 care needs on the psychiatric, physical and social wellbeing related domains (19). Eight psychiatric symptoms were calculated with scores from the Positive and Negative Syndrome Scale (PANSS) (25,26,26,26), an interview assessing clinical remission and the Health of the Nation Outcome Scale (HoNOS) (27), containing 12 items ranging from 0 (no problem) to 4 (severe problem) assessed by clinicians. Eight physical care needs were calculated with the Subject Response to Antipsychotics questionnaire (SRA-34) (28), a self-report questionnaire that measures (side) effects of pharmacotherapy containing 34 items on a 3-point scale. Physical indicators (i.e., blood pressure, BMI and waist circumference) and a blood test (glucose, hemoglobin A1c, LDL cholesterol, triglycerides and prolactin) were also included (23). Seven care needs regarding social wellbeing were calculated with the HoNOS (27) and the Manchester Short Assessment of Quality of Life (ManSA; (29), a self-report questionnaire containing 16 items on a 7-point Likert scale. All care needs were dichotomized (no care need/ care need) to yield an identical graphic representation as provided by TREAT for each participating patient in their consultation.

Clinical decision-making outcomes

We modified the *Clinical Decision-making in Routine Care* (CDRC) staff questionnaire (permission granted by the original authors (11)), to assess aspects of clinical decision-making. The original version contains 12 categories, rated as either “not discussed”, “discussed without a decision” or “discussed with a decision”. The translated and modified version of the CDRC used for this trial contained the same 23 TREAT identified care needs. The feasibility of this modified questionnaire was tested during a pilot study and deemed appropriate (19). The CDRC was filled in by clinicians directly after every consultation. Clinicians indicated which care needs were discussed and if/which treatment decisions were made for these needs. For each specific care need, it was scored whether the treatment decision was evidence-based.

Analysis

First, descriptive statistics were used to analyze patient characteristics. The baseline characteristics of the patients in both TAU and TREAT conditions were compared using independent-samples t-tests (age, care needs and duration of illness) or Chi-Square (χ^2) tests (gender and diagnosis), two-sided with a significance level of $\alpha = 0.05$. The percentage of discussed care needs in consultations (over identified care needs in the ROM assessment) was calculated. This statistic was the primary outcome and assumed to increase. The percentage of evidence-based treatment decisions (over identified care needs in the ROM assessment), served as the secondary outcome, and was also assumed to increase. A multilevel analysis was used to compare the TAU conditions (A and C phase) to the TREAT condition (phase B). A two-level linear mixed model was built for both the primary outcome and secondary outcome measure. Clinicians were modeled as level 2, and patients were modeled as level 1. To account for the ABC design, both TAU 1 (1, 0, 0) and TAU 2 (0, 0, 1) were dummy coded and added to the model as fixed effects. A Random effect was added for the intercepts at level 2. All statistical analyses were tested against a 0.05 significance level and performed using the Statistical Package of the Social Sciences (SPSS), version 27 (30).

RESULTS

Demographics and clinical characteristics

Clinicians participated with a total of 166 consultations, of which $n=65$ in TAU 1 (A), $n=65$ in the TREAT phase (B), and $n=36$ in TAU 2 (C). The unequal distribution can be attributed to the drop-out of clinicians (3 dropouts for the TREAT condition and 7 for the second TAU condition), with $n=17$ clinicians completing the trial. These drop-outs were the result of job changes or because no patients from their caseloads who were scheduled for treatment plan consultations could be included. TREAT reports were generated for all 65 consultations in the TREAT condition, indicating appropriate intervention fidelity. Compared to the overall population in regular PHAMOUS screenings, our sample contained slightly more men (69.9% vs 65.8%), was slightly older (49.2 vs 45.1), and had a longer average duration of illness (23.3 vs 17.6 years) (23). No significant differences were found between conditions in age, gender, or diagnosis (see table 1a), except for more

schizoaffective diagnosis disorder in the TREAT condition compared to TAU2. No significant differences were found in identified care needs between all phases (see table 1a), which enabled a direct comparison between the three phases on the percentages of discussed care needs and the percentages of evidence-based treatment decisions.

Table 1a. Demographics and clinical characteristics of participants (n=166)

Demographics	TAU 1 Mean	TREAT Mean	TAU 2 Mean	p-value / χ^2
Age years (SD)	48.3 (9.5)	47.8 (10.8)	48.2 (11.8)	0.95
Gender male, % (n)	64.1 (41)	73.8 (48)	77.8 (28)	0.28
Illness duration years (SD)	23.6 (10.8)	19.7 (11.7)	24.5 (12.2)	0.09
Diagnosis % (n)	TAU 1 Mean	TREAT Mean	TAU 2 Mean	χ^2
Substance induced	12.1 (8)	10.8 (7)	14.3 (5)	0.92
Schizophrenia	49.0 (32)	53.8 (35)	65.6 (23)	0.55
Schizophreniform Disorder	3.0 (2)	0 (0)	2.9 (1)	0.16
Schizoaffective Disorder*	22.3 (14)	12.3 (8)*	0 (0)*	0.06
Delusional Disorder	0 (0)	1.5 (1)	2.9 (1)	0.47
Psychosis NOS	4.5 (3)	6.2 (4)	0 (0)	0.31
Definitive diagnosis missing	9.1 (6)	15.3 (10)	14.3 (5)	0.58
Care Needs	TAU 1 Mean	TREAT Mean	TAU 2 Mean	p-value
Psychiatric (range 0-8)	1.2 (1.2)	1.3 (1.1)	1.2 (0.98)	0.98
Physical (range 0-8)	3.7 (1.5)	3.9 (1.5)	3.8 (1.3)	0.74
Psychosocial (range 0-7)	1.2 (1.5)	1.2 (1.7)	1.2 (1.4)	0.99
Total (range 0-23)	5.7 (2.4)	6.1 (2.5)	6.0 (2.4)	0.68

* significant difference between two conditions

SD = standard deviation

Table 1b. Percentage of patients with care needs (dichotomized) in all measurements (n = 166)

<i>Psychiatric Care Needs</i>	Need %	Discussed %
Positive Symptoms	41.3	93.5
Negative Symptoms	41.1	81.0
Substance Use	28.8	73.7
Depressive Symptoms	16.0	83.3
Anxiety	12.8	73.7
Agitation	0	0
Compulsive Symptoms	1.5	0
Self-harm	1.5	100
Psychiatric total average	15.3	83.3
<i>Physical Care Needs</i>	Need %	Discussed %
Bodyweight	91.3	61.6
Hyperlipidemia	78.0	61.2
Smoking	59.4	59.8
Anticholinergic Side Effects	57.9	17.1
Hypertension	51.0	45.6
(Pre)diabetes Type II	50.9	46.4
Sexual function disorder	50.4	50.0
Movement disorder	39.6	44.7
Physical total average	47.1	49.3
<i>Social Wellbeing Care Needs</i>	Need %	Discussed %
Sexuality	29.7	62.9
Social relationships	26.6	83.8
Housing	21.6	70.0
Daytime activities	13.8	89.5
Intimacy	21.1	69.2
Personal safety	11.3	57.1
Family support	6.5	87.5
Social wellbeing total average	17.4	75.9

Discussed care needs

The percentage of discussed care needs in the TREAT condition (see table 2) was significantly higher compared to both TAU conditions ($\beta = 20.2$, $SE = 5.2$, $p = 0.00$ and $\beta = 15.8$, $SE = 5.4$, $p = 0.01$). When analyzing the subdomains no differences were found between the percentage of discussed psychiatric care needs between TREAT and both TAU conditions ($\beta = 15.0$, $SE = 8.4$, $p = 0.08$ and $\beta = 11.2$, $SE = 7.3$, $p = 0.13$). A significant increase was found between TAU 1 and the TREAT condition ($\beta = 24.5$, $SE = 5.5$, $p = 0.00$) but a non-significant difference was found between the TREAT and TAU 2 condition ($\beta = 15.6$, $SE = 8.0$, $p = 0.06$). A non-significant effect was observed in the percentage of discussed care needs regarding social wellbeing being between TAU 1 and the TREAT condition ($\beta = 13.9$, $SE = 8.9$, $p = 0.12$), but a small significant effect was observed between TREAT and TAU 2 ($\beta = 21.8$, $SE = 10.4$, $p = 0.04$).

Evidence-based treatment proposals

The percentage of evidence-based treatments decisions for care needs was significantly higher in the TREAT condition (see table 2) compared to both TAU conditions ($\beta = 16.7$, $SE = 4.8$, $p = 0.00$ and $\beta = 16.0$, $SE = 5.1$, $p = 0.01$). On the subdomain of psychiatric care needs no significant differences were observed between both TAU and the TREAT condition ($\beta = 4.7$, $SE = 8.7$, $p = 0.60$ and $\beta = 4.1$, $SE = 9.8$, $p = 0.68$). The percentage of evidence-based treatment decisions for physical care needs was significantly higher in the TREAT condition compared to both TAU conditions ($\beta = 4.7$, $SE = 8.7$, $p = 0.60$ and $\beta = 4.1$, $SE = 9.8$, $p = 0.68$). A significant effect of TREAT on the percentage of evidence-based treatment decisions for identified care needs regarding social wellbeing was observed compared to TAU 1 ($\beta = 11.5$, $SE = 4.9$, $p = 0.02$), but not between the TREAT and TAU 2 ($\beta = 4.7$, $SE = 6.0$, $p = 0.44$).

Table 2. Total mean scores discussed care needs percentages and percentages of evidence-based treatment decisions

	TAU 1 Mean (SD)	TREAT Mean (SD)	b (95% CI)	p-value
Discussed total % **	51.1 (27.4)	70.4 (23.2)	20.2 (9.3, 31.1)	0.00**
Discussed psychiatric %	77.3 (35.1)	89.8 (27.9)	15.0 (-1.8, 32.0)	0.08

Discussed physical % **	38.3 (34.2)	62.0 (31.7)	24.5 (13.6, 35.4)	0.00**
Discussed social wellbeing %	72.2 (37.9)	86.1 (28.1)	13.9 (-3.7, 31.6)	0.12
EVB treatment total % **	18.3 (21.4)	33.4 (32.0)	16.7 (6.9, 26.6)	0.00**
EVB psychiatric %	23.2 (37.9)	28.2 (41.9)	4.7 (-12.7, 22.0)	0.60
EVB physical % **	16.5 (24.6)	34.1 (33.7)	19.6 (8.2, 31.0)	0.00**
EVB social wellbeing % *	4.6 (15.2)	15.0 (32.5)	11.5 (1.55, 16.6)	0.02*
	TREAT M (SD)	TAU 2 M (SD)	b (95% CI)	p-value
Discussed total % *	70.4 (23.2)	55.6 (25.1)	15.8 (4.0, 27.6)	0.01*
Discussed psychiatric %	89.8 (27.9)	80.6 (35.0)	11.2 (-3.4, 25.8)	0.13
Discussed physical %	62.0 (31.7)	45.9 (31.7)	15.6 (-0.4, 31.6)	0.06
Discussed social wellbeing % *	86.1 (28.1)	64.3 (37.7)	21.8 (1.0, 42.6)	0.04*
EVB treatment total % **	33.4 (32.0)	19.3 (20.2)	16.0 (5.4, 26.7)	0.00**
EVB psychiatric %	28.2 (41.9)	24.3 (36.1)	4.1 (-15.4, 23.5)	0.68
EVB physical % **	34.1 (33.7)	20.3 (25.2)	15.9 (4.9, 26.9)	0.00**
EVB social wellbeing %	15.0 (32.5)	7.7 (15.3)	4.7 (-7.3, 16.6)	0.44

SD, standard deviation

* significant at $p = 0.05$

** significant at $p = 0.01$

DISCUSSION

The first aim of this study was to examine whether clinicians working with the clinical decision aid (CDA) named Treatment E-Assist (TREAT) discuss more of their patient's care needs compared to usual treatment. A multilevel analysis revealed a significant increase in the number of identified care needs being discussed when TREAT was used. These results confirm findings from a qualitative assessment in which most clinicians indicated that TREAT made routine outcome monitoring data (ROM) easier to discuss during clinical encounters due to improved structure of the report and a more appealing graphical representation of the data, which subsequently improved the discussion with patients over prevalent issues (20). As was found in other studies (11,12), existing psychiatric care needs were most frequently discussed in clinical encounters. TREAT did not significantly increase the number of psychiatric needs being discussed in the consultations. One could

argue that psychiatric needs have always been the focus of treatment for severe mental illness. Therefore, a clinical decision aid such as TREAT does not affect these often discussed needs. In contrast, physical care needs are highly prevalent and may remain undisclosed and untreated in psychosis care (6,7,13). This was confirmed by our results, as physical care needs account for more than half of all needs, yet are discussed significantly less often compared to psychiatric (34.0%) and social wellbeing related care needs (26.6%). Our findings suggest that TREAT shifts the conversation more towards physical or social wellbeing related needs, for example by initiating conversations about sensitive or intimate topics which might otherwise have remained undisclosed (20). These topics are important as cardio-metabolic risk factors as well as social isolation and loneliness are known to contribute to a lower quality of life and severely reduced life expectancy (31,32,33).

The second aim of this study was to examine whether clinicians working with TREAT agree on more evidence-based treatment decisions compared to usual treatment. Research synthesis and guideline development in mental healthcare is an advanced and well-developed process, but the dissemination of evidence-based guidelines into daily clinical practice is much less organized and lagging behind (15). With TREAT, an active strategy was developed to improve the implementation of guidelines in psychosis care. The use of TREAT resulted in a significant increase in the number of evidence-based treatment decisions for identified care needs compared to usual treatment. The first potential reason for this increase is the evidence-based treatment recommendations. While some clinicians actively used the recommendations during their consultations, others felt they had sufficient knowledge about existing treatment options (20). An alternative explanation could be the graphic representation of identified care needs by TREAT. Issues that might otherwise be overlooked are now more actively discussed and a course of action for treatment could then be suggested. No significant differences were observed for psychiatric needs, but the number of evidence-based treatment decisions for physical needs nearly doubled. The number of evidence-based treatment decisions for social wellbeing-related needs was considerably lower. Fewer evidence-based psychological interventions are sometimes available for these needs in regional care, for example due to lack of trained practitioners. While other forms of organized care such as community centers or assisted living accommodations

are not within the scope of this study, these needs can be accommodated. As a results, TREAT has fewer recommendations for social wellbeing-related needs compared to recommendations for psychiatric and physical needs. Nevertheless, a threefold increase was observed when TREAT was used compared to usual treatment before the intervention.

Clinical implications

TREAT changed the content of the conversations by addressing a wider array of topics such as physical health issues and challenges related to social wellbeing, that would otherwise go unnoticed in treatment plan meetings (11). For example, cardio-metabolic risk factors associated with the use of antipsychotic medication are notoriously difficult to treat (13,34). ROM can be used to monitor these risk factors, but the results do not always translate to actions in daily clinical practice (6,7). Combining ROM with progress feedback has the potential to improve patient outcomes in clinical practice (35). TREAT facilitates this process by improving the integration of ROM results in consultations, leading to more discussed care needs, especially the physical ones, which are most prevalent and often insufficiently considered. Increased negotiation with personalized treatment recommendations resulted in an increase in evidence-based treatment decisions. In this way TREAT also contributes to the implementation of guidelines that have the potential to improve clinician's performance and patient outcomes in mental healthcare (36,37). Where previous efforts of guideline implementations often failed to increase adherence (38), TREAT offers a practical, real-world implementation blueprint for precision medicine and guideline implementation in psychosis care. In this trial the effects of TREAT on shared decision-making and their overall satisfaction with consultations will also be examined from a patient point of view. These results are published in a separate paper.

Strength and limitations

To our knowledge, this is the first study in psychosis care to evaluate the effects of a CDA on clinical decision-making. Our results contribute to the literature on decision support in general and in particular in psychiatry where deployment of CDAs is still limited (16). This study presents an effective way to improve the incorporation of

ROM results in daily clinical practice. Furthermore, an active and effective strategy for guideline implementation during clinical encounters is demonstrated. With 27 clinicians from four different mental healthcare institutions participating with 166 different patients in their clinical encounters during two years, we managed to collect a diverse clinical sample of clinicians working in psychosis care. A potential limitation of this study is a possible selection bias in participating clinicians. We tried to recruit clinicians who were skeptical towards TREAT, but we cannot rule out an oversampling of clinicians with more favorable attitudes. Many CDAs are used suboptimal in clinical encounters (17), we checked if TREAT reports had been generated by clinicians for the corresponding consultations, but no additional observations were made to assess intervention fidelity.

Conclusions

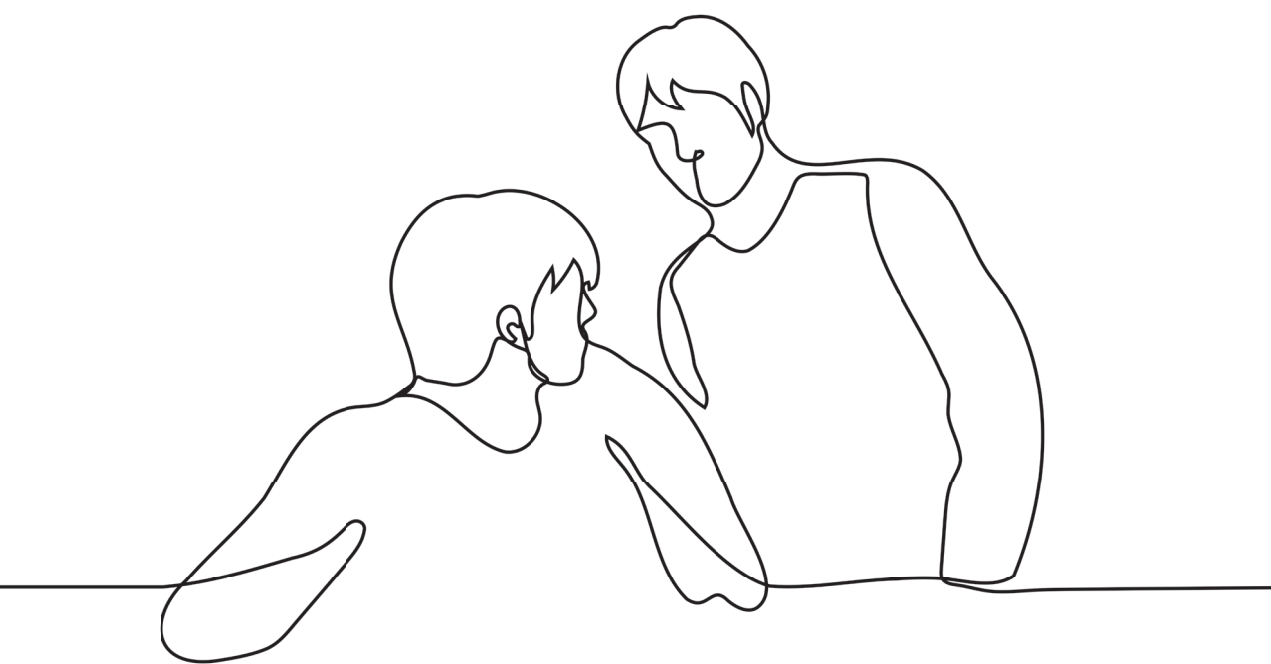
This study examined the effects of TREAT, a clinical decision aid in psychosis care, on clinical decision-making. We expected TREAT would improve discussion about existing care needs and increase the number of evidence-based treatment decisions for those needs. TREAT improves discussion about physical and social wellbeing-related care needs. It also increased the number of evidence-based treatment decisions for physical needs, which otherwise can remain untreated. TREAT improves the integration of ROM results in daily clinical practice while at the same time serving as guideline implementation. Our findings add to the limited knowledge about decision support in mental healthcare and provide a real-world example for the implementation of precision medicine in psychosis care.

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Chapter 8

General Discussion

The aims of this dissertation

The main aims of this dissertation were to test a clinical decision aid (CDA) called TRTreatment E-AssisT (TREAT) in the regular clinical practice of psychosis care and to study its effects on shared and clinical decision-making. First, the main findings of the chapters of this dissertation will be briefly summarized. Next, these findings will be integrated with acquired knowledge and lessons learned in this PhD project to discuss and reflect on the implementation of TREAT and its complexities in daily clinical practice. Finally, the limitations of this research will be placed into context and future perspectives on decision support in mental healthcare will be discussed.

The development of TREAT and the main findings of the TREAT trial

This dissertation starts with a general overview of the current state of decision support in healthcare and specifically addresses the use of CDAs in mental healthcare (**Chapter 2**). Although certain types of digital innovations are making headway, in mental healthcare decision support and CDAs are still in the early stages of their development and implementation. The first assessment of TREAT in a pilot study (**Chapter 3**), demonstrated that the application was ready for testing in a clinical trial. To gain insight in the prevalence of the various care needs and their development over time, the algorithms we designed for TREAT were used to assess care needs during a four-year period with routine outcome monitoring (ROM) data from the PHAMOUS screening (**Chapter 4**). Physical care needs were most prevalent, relative to psychiatric and social wellbeing related care needs, and more persistent over time. This first part of the dissertation provided the basis for the second part, in which the effects of TREAT were studied in a clinical setting.

Most clinicians who worked with TREAT in the trial and participated in the qualitative assessment (**Chapter 5**) experienced the application as beneficial to their consultations. The graphical representation of ROM results improved the dialogue about patients' care needs during consultations. Opinions about the added value of the guideline-based treatment recommendations provided by TREAT varied, but nearly all interviewed clinicians experienced more shared decision-making (SDM) while using TREAT during their consultations. These findings about SDM were not

replicated in the TREAT trial (**Chapter 6**), which can most likely be attributed to the already high levels of SDM as assessed with the DCS-scale, experienced by patients in both the experimental and control conditions. Despite initial concerns about a potential depersonalization of interactions, the consultations were also highly valued by patients in both treatment conditions. These findings suggest that the introduction of TREAT did not decrease the perceived quality of the clinical encounters. In contrast, the use of TREAT improved clinical decision-making, as reflected in the increased amount of discussed care needs as well as the increased amount of evidence-based treatment decisions when the application was used (**Chapter 7**). In sum, TREAT provides an interesting case study for decision support in psychosis care.

Connecting routine outcome monitoring to routine care

In 2007 a ROM screening protocol called the Pharmacotherapy Monitoring and Outcome Study (PHAMOUS) was initiated in multiple mental healthcare institutes in the Northern Netherlands. The goal of PHAMOUS was to improve care for people with a psychotic illness, by annually screening their (mental) health and needs. The results of the screening provide input for treatment plan consultations in which clinicians and patients collaboratively explore treatment options and make a subsequent treatment plan. The collected data is also used for scientific research aiming to improve the care process. Based on this data, two earlier studies showed that care needs identified by PHAMOUS were often not represented in the actual treatment plans of patients (1,2). Clinicians sometimes struggled with the interpretation and integration of the screening results, leading to large differences in the way the PHAMOUS data is used (2). This was emphasized during the recruitment phase of our trial, as some teams had already implemented well-structured screening and feedback routines while other teams used the TREAT trial to implement a more systematic approach. During a flight from Amsterdam to Colorado Springs, clinicians and researchers conceptualized the TREAT application in an attempt to improve the systemic feedback of the PHAMOUS results to routine care. The systematic feedback of ROM results is an evidence-based practice (3), for which TREAT can offer support (4).

One of the aims of this dissertation was to examine whether TREAT can improve the integration of ROM results into regular clinical psychosis care. Before discussing

our findings in relation to this aim, it is important to recognize that there will never be a perfectly reliable, valid, and sufficient assessment tool for each individual patient (4). The instruments that comprise the ROM screening can be reliable and valid, but at the same time only provide a snapshot of a complex medical condition that characterizes a non-linear recovery trajectory. We will circle back to this recovery oriented approach later in this discussion. TREAT uses all available instruments and measurements from the PHAMOUS screening for a snapshot of psychiatric, physical and social wellbeing related care needs. At the same time TREAT is bound to the assessments of PHAMOUS, meaning that for example personal recovery oriented care needs such as meaningfulness and spirituality, are currently not represented.

During the recruitment of healthcare professionals for the clinical trial of the TREAT study in 2017, some were skeptical about the added value of computerized decision support in psychosis care. Concerns were expressed that a mechanistic adoption of guideline-based decision aids would result in rigid communication because procedures would divert time from the regular therapeutic process or create information overload leading to confusion. Clinicians feared potential depersonalization of interactions, where the people in care would be reduced to mere numbers and graphs. But despite some initial skepticism, many clinicians were open to a novel approach in their clinical encounters. A common remark was that TREAT was the missing piece of the PHAMOUS screening.

TREAT's graphical representation of these often prevalent and persistent care needs (**Chapter 4**) made them easier to discuss (**Chapter 5**), which subsequently occurred more frequently (**Chapter 7**). For example, clinicians were able to include intimate topics such as sexuality or sexual function disorders in their communications more often. Furthermore, care needs related to chronic physical illnesses, which are four times more prominent in people with psychotic illnesses compared to the general population (5), were more often discussed when TREAT was used. In this way TREAT contributes to an improved discussion about important topics which otherwise can remain undiscussed and untreated. This is a meaningful first step that solidifies the potential of decision support in regular clinical psychosis care by improving the integration of ROM results during consultations.

Clinician's perspective on decision support

With evidence suggesting that TREAT improves the discussion about care needs (**Chapter 7**), we can now take a closer look at a second aim of this dissertation and examine the effects of TREAT on shared and clinical decision-making. Uncertainty plays an inherent role in the decisional process in mental healthcare, both for clinicians as well as patients (6,7). Clinicians can face uncertainty when deciding upon a diagnosis, assessing symptoms, or finding adequate treatment. To be able to do this, clinicians rely on observations and self-reports. This changes due to the cultural digital advancements which lower the threshold for innovative technologies, such as CDAs into mental healthcare (8). These technologies can assist a process-based care approach, which targets the biopsychosocial processes and facilitates a match with the patient's specific goals and situation (9). Our current understandings of the effects of CDAs on clinical decision-making in mental healthcare (10-12) is limited in comparison with other medical fields (13). Only a few studies make direct comparisons between treatment decisions with a CDA and without, as in regular clinical judgment decisions (14). Our trial adds to the current knowledge gap by comparing regular clinical treatment advice and CDA assisted decision-making (**Chapter 7**). We observed that evidence-based treatment decisions nearly doubled (from 18.3% to 33.4%) when TREAT was used. This observed increase disappeared after the same clinicians stopped working with TREAT, which solidifies the continuous availability of the application. Our multi-method approach (combining quantitative and qualitative research) helps us place these findings in a more nuanced perspective. Opinions about the usability of the treatment recommendations of TREAT varied (**Chapter 5**). Some clinicians did not use the recommendations at all during their clinical encounters, others used them mostly to validate their own assessments and some did use them for discussion with their patients. Therefore, the availability of TREAT might be more relevant for the observed increase in evidence-based treatment decisions, than the actual treatment recommendations proposed by TREAT. Increased awareness of and discussion about the identified care needs and adequate forms of treatment, is potentially more relevant.

Decision support from a patient point of view

We have reflected on the uncertainty that clinicians face in the decisional process. Now we will take a closer look at the uncertainty patients experience when consenting on treatment. The degree of uncertainty that patients face when making difficult healthcare decisions is called decisional conflict and can be measured with the decisional conflict scale (DCS) (15). Decisional conflict is seen as a reliable measure for the level of shared decision-making (SDM) as it is closely connected to the interaction between patient and clinician (16,17). Moreover, the questions and subscales of the DCS accurately measure the degree in which TREAT clarified values, delivered information and provided support about decisions and treatment options. Interestingly, our mixed method approach led to conflicting findings. All interviewed clinicians in the qualitative study reported more shared decision-making with their patients when TREAT was used (**Chapter 5**). The experienced increase in SDM was not confirmed in our trial as patients experienced high levels of SDM, both with or without TREAT (**Chapter 6**). CDAs such as TREAT seem to be most effective in increasing SDM in clinical settings with more acute treatment decisions surrounded by high levels of uncertainty and decisional conflict, for example in oncology (18), neurology (19), or orthopedics (20). Based on our findings we would not recommend the use of TREAT for the sole purpose of increasing SDM for people receiving care in FACT teams. However, tools such as TREAT might be effective in mental healthcare for example in the treatment of people with personality disorders, who tend to experience more decisional conflict and less stable therapeutic alliances compared to people with a psychotic illness (7).

Despite the lack of an observable increase in SDM, TREAT can benefit patients in other ways such as increasing the amount of specific care needs being discussed during consultations (**Chapter 5 & 7**). The graphic representation of these needs made intimate topics, for instance sexuality and sexual dysfunction, easier to discuss. Moreover, TREAT increased the discussion about physical care needs which, as was addressed in the introduction, can sometimes remain unnoticed and as result untreated. A recent report from the Dutch Care Institute revealed that only 17% of all patients with a psychotic illness in the Dutch mental healthcare system receive an annual somatic screening (21). The obvious first step would be to increase annual screenings, but our research indicates that screening

alone does not automatically leads to appropriate treatment for physical care needs. These needs require a multifaceted collaborate approach with general practitioners and settings outside of mental healthcare such as community centers or gyms. Taken together, the use TREAT shows an encouraging increase in the number of evidence-based treatments for many of these needs (**Chapter 7**). A follow-up study could examine how this benefits patients on more long-term clinical outcomes such as their symptoms, specific physical health parameters and factors related to their social-wellbeing. In sum, these findings reinforce the use of TREAT in psychosis care. CDAs, such as TREAT, can support and enhance decision-making, but they will never be able to fully replace the value of clinicians' adaptive problem-solving abilities, clinical intuition and ability to translate evidence to a specific clinical context. Moreover, CDAs can never fully replace the personal input and preferences of patients who oftentimes have been in care for many years and are generally very knowledgeable about their illness. Their commitment and motivation to specific interventions is pivotal to the outcome, which requires an ongoing open dialogue.

A connected approach to implementation

It takes healthcare innovations on average 17 years to go from research to implementation (22). More than half of all innovations never reach the clinical practice at all (23). Main reasons for unsuccessful implementation of novel interventions are for instance: a lack of knowledge or motivation by clinicians, limited applicability in clinical practice, a perceived lack of utility and organizational constraints (23). In order to prevent some of these issues, the end-users of TREAT were involved in all developmental stages, which increased the likelihood of successful adoption in clinical practice (24). Clinicians were part of the conceptualization of the TREAT algorithms and participated in multiple stages of the evaluation of TREAT for future improvements (**Chapter 3**). Two other important factors for successful implementation are usability and time efficiency (24). In other words, the tool needs to be easy to use and has to save clinicians more time compared to their regular way of working, TREAT fits both criteria reasonably well (**Chapter 5**). We also adopted the recommended strategy to increase the uptake of TREAT in existing workflows by incorporating the application into the electronic patients records (8,10). All conditions seem in place to ensure TREAT will indeed

reach clinical practice. We believe in a bottom-up approach in which clinicians experience the merit of TREAT during their own practice. During the trial we have experienced that it usually takes one dedicated clinician to motivate the rest of the team to start working with the tool.

Besides examining the implementation of decision support in the form of TREAT in daily clinical practice of psychosis care, another aim of this dissertation was to investigate whether TREAT can support guideline implementation. Our trial showed a strong increase in the number of evidence-based treatments being initiated (**Chapter 7**). However, the treatment recommendations are only as good as the current treatment services. For multiple teams, especially in more rural areas, many of the recommended interventions were unavailable. For example, psychomotor therapy (PMT), cognitive behavioral therapy (CBT), eye movement desensitization and reprocessing (EMDR), individual placement and support (IPS) and housing first were often mentioned as not being available (**Chapter 5**). This is an important message to all stakeholders involved in increasing evidence-based practice in routine care. There is an ongoing responsibility to keep the content of TREAT up to date with the newest evidence from guidelines and standards of care, as well as a responsibility to maintain a continuous ROM program for all patients in care. At the same time it might take multiple years to increase the availability of the aforementioned resources and for new interventions, as discussed earlier, to reach clinical practice. In sum, we would recommend implementing a CDA, such as TREAT, in psychosis care, given a suitable ROM program is present. Implementation supports the integration of ROM results and uptake of guidelines in routine care. TREAT is still a work in progress and can be improved in several ways, including some out of the box solutions.

Where do we go from here?

This dissertation has provided a clinical example of the use of CDAs, such as TREAT, in treatment of people with a psychotic illness. At the same time TREAT is still a work in progress and many suggestions have been made throughout this research project in order to improve the application. One of the concerns expressed by clinicians was the overemphasis on problems and more negative aspect instead of the improvements in treatment. From a recovery point of view, motivation and resilience are just as important in the outcome of interventions. Too

many repetitive alerts and warnings can also result in alert fatigue or information overload for the users of CDAs (10,25). The incorporation of graphically displaying positive health trends in treatment would be a first step to improve TREAT. This can help shift the focus from care needs and a disease oriented approach towards a more optimistic recovery oriented or positive health approach (26,27). In this way TREAT serves as a continuous feedback loop, not just to identify care needs but also to evaluate and monitor the progress of the treatment decisions from previous consultations. A next step could be a connection to the experienced sampling method (ESM) (28). One or multiple important care needs could be chosen for in-depth monitoring by using smart devices such as mobile phones. In this way TREATs ROM based clinical snapshot could be enriched with real-world data, to monitor the progress of issues needing treatment. This ties in with a recent report from the World Economic Forum, which advises wearable devices and apps to monitor treatment progress and encourage an active lifestyle for people with a severe mental illness (29). Furthermore, this report calls for innovative digital applications in mental healthcare, which are currently being developed and tested (12). Integrating these different innovations into a single platform will be one of the challenges going forward. TREAT could serve as a potential digital platform embedded in an electronic patient record which connects these different forms of innovation. Together with patients, clinicians, peer support workers and other researchers, this platform could be built for future use. In this way, David Gelernter's predictions about a digital revolution, as described in the introduction, might finally start to come to fruition in mental healthcare.

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SUMMARY

This dissertation describes the use of a clinical decision aid (CDA), named Treatment E-AssisT (TREAT), in the treatment of people with psychotic illnesses. In the first part, the current state of decision support in mental healthcare, as well as the development of TREAT and the prevalence of existing care needs are discussed. The second part describes the outcomes of a clinical trial investigating the effects of TREAT on shared and clinical decision-making, as well as a qualitative assessment of the experiences of clinicians who worked with TREAT.

Part I: Background and development of TREAT

Chapter 1 describes the upcoming global digital revolution and its impact on the healthcare system. Digital innovation will also start to make headway in mental healthcare. Computerized clinical decision aids will be part of this innovation wave but are at the moment rarely used in routine care. Decision aids exist in many forms and have the ability to specify the medical decision at hand. They also recommend treatment and inform about the pros and cons of each option. The next chapters describe the developments of TREAT in psychosis care.

Chapter 2 starts with a brief case study illustrating some of the difficulties which can arise when establishing the needs for care and subsequent treatment for people in psychosis care. The use of routine outcome monitoring (ROM) can support the identification of these care needs. In this chapter the ROM screening called the PHarmacotherapy Monitoring and OUtcome Study (PHAMOUS) is introduced. The PHAMOUS screening is used in multiple mental healthcare institutions in four (out of twelve) Dutch provinces. Several studies have demonstrated that the uptake of the PHAMOUS results in routine psychosis care can be improved. The dissemination of evidence-based information from guidelines and standards of care can also be improved in psychosis care. A clinical decision aid such as TREAT combines needs experienced by patients, as identified by the PHAMOUS screening, with information from guidelines and care standards. The use of CDAs has proven beneficial in various medical disciplines, for instance by increasing shared decision-making or improving clinical outcomes. In mental healthcare, only few of these tools have actually been tested in clinical practice. The TREAT trial will add to our general understanding of decision support in mental healthcare, and specifically in psychosis care.

The goal of **Chapter 3** was to explain the developmental process of TREAT and to describe the results of the first clinical evaluation. The underlying algorithms of TREAT were established by focus groups containing psychiatrists, psychologists, nurse practitioners, and researchers. From all the PHAMOUS measurements and instruments, a total of 23 care needs were derived. Treatment recommendations were added based on guidelines and standards of care. In order to test the feasibility of the newly developed TREAT tool for a clinical trial, six clinicians participated in a pilot study. These clinicians found TREAT easy to use and useful for routine care. They expected TREAT to have a positive impact on their clinical practice, but were unsure if the application could improve specific patient outcomes. Based on all the input from participating clinicians, TREAT was improved for the upcoming trial. A translated and modified version of the Clinical Decision Making in Routine Care (CDRC) questionnaire was also tested and approved for use in the trial.

Chapter 4 describes a longitudinal analysis which aims to gain a greater understanding of the prevalence and development of care needs, as identified by TREAT, from patients receiving FACT care in four mental healthcare institutions in the Northern Netherlands. Furthermore, the relationship between these care needs and care consumption, as well as care needs and evidence-based pharmacotherapy, were presented. Our sample included more than 2000 patients and 5000 measurements over a four year period. By using the same structure as TREAT three domains were distinguished: psychiatric, physical and social-wellbeing related care needs. Physical care needs were about twice as common compared to psychiatric and social-wellbeing related care needs. Positive (54.3%) and negative symptoms (50.1%), needs relating to bodyweight (90.2%), hyperlipidemia (81.8%) and social relationships (48.9%) were among the most common needs. While the chance of experiencing some of the psychiatric and most of the social-wellbeing related care needs decreased with subsequent years in care, the chances of experiencing physical care needs remained the same. Patients received on average 25.4 hours of outpatient mental healthcare per year. As expected, people with the highest needs received the most mental healthcare potentially explaining the positive relation between many of care needs with care consumption. Defining and identifying care needs based with PHAMOUS assist routine care in order to accommodate people's care needs on these different domains and help institutions with appropriate care allocation.

Part II: Clinical evaluation of TREAT

The goal of **Chapter 5** was to assess the perspectives of clinicians on TREAT. A total of eight psychiatrists and five nurse practitioners which worked with TREAT multiple times, were interviewed in-depth about their experiences. Most of them found TREAT easy to use and beneficial to their consultations. However, some were skeptical or stated that the application decreased the quality of their clinical encounters. Five recurrent themes were identified from the interviews which increased our understanding of how TREAT was experienced. The first theme was the graphic representation of the PHAMOUS data. The data was better structured and more appealing for most clinicians which made the results easier to discuss. The opinions about the second theme, TREAT's treatment recommendations, were mixed. Some clinicians used the recommendations to start a discussion about potential treatments or to support their clinical reasoning while others felt no need for additional recommendations because they were sufficiently aware of all available treatments. The third theme revolved around TREAT's contextual factors such as the existing infrastructure, routines or feedback procedures. Structured and complete PHAMOUS screenings were a prerequisite for the use of TREAT, along with sufficient treatment resources in order to follow up on recommendations. The fourth recurring theme was the effect of TREAT on patients. On the one hand, TREAT gave patients a new sense of ownership over the results of their screenings and made the results as well as intimate topics, easier to discuss. On the other hand, the results were sometimes confrontational or confusing. The fifth theme was shared decision-making (SDM). While opinions varied on most themes, nearly all clinicians experienced a perceived increase in SDM when TREAT was used.

Our goal in **Chapter 6** was to investigate this reported increase in SDM. SDM is considered highly desirable in the treatment of people with severe mental illness, yet is not always a regular occurrence. In total 187 patients participated in our trial. They either received treatment as usual before in the first phase, or worked with TREAT in the second phase, or received treatment as usual in the last phase of the trial. Despite our findings from the qualitative study, we were not able to replicate these findings. Patients experienced high levels of SDM as well as high satisfaction with the consultations in all phases of the trial. Our findings could partially be explained by the relatively long duration of illness in our sample (mean: 23 years), which makes most participants very knowledgeable about their illness and may

have strengthened the therapeutic alliances with their clinicians. At this point in time, we would not recommend TREAT for the sole purpose of increasing SDM for people receiving care in FACT teams. It would be worthwhile to investigate if CDAs, such as TREAT, might increase SDM in other mental healthcare settings with higher baseline levels of decisional conflict.

While TREAT might not increase SDM, it could influence the decisional process in other ways. The aim of **Chapter 7** was to investigate the effects of TREAT on clinical decision-making. In order to investigate this, we used CDRC questionnaire which was validated in the pilot study. This questionnaire was filled out by clinicians to assess which of the potential 23 care needs identified by TREAT, were discussed and if a decision had been made. A total of 27 clinicians participated with a total of 166 consultations throughout the three phases of the trial. In the first treatment as usual phase 51.1% of all identified care needs were discussed during the consultations. In the TREAT condition this number of discussed care needs increased significantly to 70.4%. In the second treatment as usual phase, when TREAT was shut off again, the number of discussed care needs decreased significantly to 55.6%. In the first treatment as usual condition an evidence-based treatment was initiated for 18.3% of all discussed care needs. This number of initiated evidence-based treatments increased significantly to 33.4% for all discussed care needs in the TREAT condition. In the second treatment as usual phase, when TREAT was shut off again, this number of evidence-based treatments significantly decreased to 19.3% for all identified care needs. In sum, we can conclude that TREAT has encouraging effects on the discussion and integration of ROM identified care needs and guideline implementation in the form of initiated evidence-based treatments.

In **Chapter 8** we reflect on our findings and theorize on how our findings can contribute in a broader context. In a world which is quickly moving into a new digital era, the field of mental healthcare is now starting to catch up with different innovative technological advancements. TREAT is an example of how technology can change the way we deliver care going forward. TREAT integrates patient data and has the potential to disseminate guidelines. With new improvements TREAT could become a digital platform connecting different forms of innovation. More importantly this dissertation provides an example of how decision support can aid mental healthcare in general and psychosis care in specific.

SAMENVATTING

Dit proefschrift beschrijft het gebruik van een klinische beslistool, genaamd Treatment E-AssisT (TREAT), voor de behandeling van mensen met een psychotische aandoening. In het eerste gedeelte wordt de huidige stand van zaken van beslissingsondersteuning in de geestelijk gezondheidszorg, de ontwikkeling van TREAT en de prevalentie van zorgbehoeften bij mensen met een psychotische aandoening beschreven. Het tweede gedeelte beschrijft de uitkomsten van een klinische trial die de effecten van TREAT op gedeelde en klinische besluitvorming onderzoekt, evenals een kwalitatieve analyse over behandelaren die met TREAT hebben gewerkt.

Deel 1: Achtergrond en ontwikkeling van TREAT

Hoofdstuk 1 beschrijft de mondiale digitale revolutie die aanstaande is en legt wat de impact zal zijn op de gezondheidszorg. Binnen de GGZ komt deze digitaliseringsslag ook op gang met verschillende digitale innovaties. Digitale beslistools zijn hiervan een voorbeeld maar ze worden nog weinig gebruikt in de dagelijkse behandelpraktijk. Beslistools bestaan in vele vormen en zijn in staat om de medische beslissing te specificeren die op dat moment gemaakt dient te worden. Daarnaast stellen ze mogelijke behandelingen voor en informeren ze over de voor en nadelen van deze behandelingen. De volgende hoofdstukken zullen verder ingaan op de ontwikkeling van TREAT binnen de psychosezorg.

Hoofdstuk 2 start met een korte casusbeschrijving die het probleem illustreert dat kan ontstaan bij het bepalen en behandelen van zorgbehoeften van mensen in de psychosezorg. Het gebruik van routine outcome monitoring (ROM) kan ondersteuning bieden aan het bepalen van zorgbehoeften. In dit hoofdstuk wordt de ROM-screening, genaamd de PHarmacotherapy Monitoring and OUtcome Study (PHAMOUS), geïntroduceerd. De PHAMOUS-screening wordt gebruikt door verschillende GGZ- instellingen in vier (van de twaalf) Nederlandse provincies. Verschillende studies hebben laten zien dat het gebruik van de PHAMOUS-data nog kan worden verbeterd in de dagelijkse behandelpraktijk. Dit geldt ook in de psychosezorg voor het dissemineren van evidence-based informatie uit richtlijnen en zorgstandaarden. Een klinische beslistool, zoals TREAT, combineert de door PHAMOUS geïdentificeerde zorgbehoeften van patiënten met informatie uit richtlijnen en zorgstandaarden. Het gebruik van beslistools heeft in verschillende

medische disciplines zijn meerwaarde getoond, bijvoorbeeld bij het verbeteren van gedeelde besluitvorming of het verbeteren van specifieke klinische uitkomsten. Slechts enkele van deze beslistools zijn momenteel getest en beschikbaar in de dagelijkse behandelpraktijk van de GGZ. De TREAT-trial zal bijdragen aan onze huidige kennis over beslissingsondersteuning in de GGZ in het algemeen en specifiek in de psychozorg.

Het doel van **hoofdstuk 3** was het beschrijven van het ontwikkelingsproces van TREAT alsmede het beschrijven van de resultaten van de eerste klinische evaluatie. De onderliggende algoritmes van TREAT zijn tot stand gekomen aan de hand van focusgroepen met psychiaters, psychologen, verpleegkundig specialisten en onderzoekers. Uit alle PHAMOUS-metingen en instrumenten kon een totaal van 23 zorgbehoeften worden geïdentificeerd. Behandeladviezen voor deze zorgbehoeften werden gebaseerd op geldende richtlijnen en zorgstandaarden. Een pilotstudie met zes behandelaren werd uitgevoerd om de haalbaarheid van een klinische trial met TREAT te onderzoeken. De behandelaren vonden TREAT gemakkelijk te gebruiken en nuttig voor hun dagelijkse behandelpraktijk. Ze hadden de verwachting dat TREAT een positieve bijdrage zou hebben op hun behandelcontacten, maar waren niet zeker of de applicatie ook een positief effect zou hebben op specifieke klinische uitkomsten. Op basis van alle input van de behandelaren, is TREAT verder doorontwikkeld voor het gebruik tijdens de klinische trial. Tevens werd een vertaalde en gewijzigde versie van de Clinical Decision Making in Routine Care (CDRC) vragenlijst, getest en goedgekeurd voor gebruik in de trial.

Hoofdstuk 4 beschrijft een longitudinale analyse met als doel het in kaart brengen van de prevalentie en de ontwikkeling van zorgbehoeften, zoals door TREAT geïdentificeerd, bij patiënten die FACT-zorg ontvangen bij vier GGZ instellingen in Noord-Nederland. Daarnaast werd ook de relatie van deze zorgbehoeften met zorgconsumptie en evidence-based farmacotherapie bekeken. De data van deze studie bestond uit meer dan 5000 metingen van 2000 verschillende patiënten over een periode van vier jaar. Net als bij TREAT werden de zorgbehoeften opgedeeld in de domeinen: symptomatische, fysieke en psychosociale zorgbehoeften. Positieve (54.3%) en negatieve symptomen (50.1%), overgewicht (90.2%), hyperlipidemie (81.8%) en sociale contacten (48.9%) zijn voorbeelden van de meest voorkomende zorgbehoeften in onze studie. Terwijl de kans op sommige psychiatrische en de

meeste psychosociale zorgbehoeften afnam met ieder jaar extra zorg, bleven de kansen op alle fysieke klachten ongewijzigd. Patiënten ontvingen gemiddeld 25.4 uur aan ambulante GGZ zorg per jaar. Zoals verwacht ontvingen mensen met de meeste zorgbehoeften ook de meeste zorg, hetgeen de vele positieve associaties zou kunnen verklaren tussen verschillende zorgbehoeften en zorgconsumptie. Het identificeren van zorgbehoeften aan de hand van ROM-data kan de dagelijkse behandelpraktijk ondersteunen in de zoektocht naar de juiste zorg.

Deel II: De klinische evaluatie van TREAT

Het doel van **hoofdstuk 5** was het beschrijven van de gebruikerservaringen van behandelaren die met TREAT hebben gewerkt in hun dagelijkse behandelpraktijk. Diepte-interviews werden afgenomen bij een totaal van acht psychiaters en vijf verpleegkundig specialisten, die meerdere keren met TREAT hebben gewerkt. De meeste behandelaren vonden TREAT makkelijk te gebruiken en een meerwaarde voor hun dagelijkse behandelpraktijk. Sommige waren echter sceptisch en een enkeling vond zelfs dat het behandelcontact in kwaliteit afnam. Er waren vijf terugkerende thema's die naar voren kwamen uit de interviews die ons een beter inzicht geven in hoe het gebruik van TREAT is ervaren. Het eerste thema was de grafische weergave van de PHAMOUS-data. De data was beter gestructureerd en visueel aantrekkelijker hetgeen de bespreking van de resultaten ten goede kwam. De meningen over het tweede thema, de behandeladviezen van TREAT, waren verdeeld. Sommige behandelaren gebruikten de adviezen om een discussie te starten over mogelijke behandelingen of om hun eigen klinisch redeneren te ondersteunen, terwijl andere behandelaren geen behoefte hadden aan extra adviezen, omdat ze voldoende op de hoogte waren van het beschikbare behandelaanbod. Het derde thema waren de contextuele factoren van TREAT zoals de bestaande infrastructuur, routines of terugkoppelingsprocedures. Een gestructureerde en complete screening is essentieel voor het goed functioneren van TREAT, samen met een goed behandelaanbod binnen instellingen om de behandeladviezen adequaat op te kunnen volgen. Het vierde terugkerende thema was het effect van TREAT op patiënten. Aan de ene kant gaf TREAT patiënten een gevoel van eigen regie over de resultaten van hun screening en werd het makkelijker om bepaalde intieme onderwerpen bespreekbaar te maken. Aan de andere kant waren de resultaten soms confronterend of was de hoeveelheid aan

data soms overweldigend. Het vijfde thema was gedeelde besluitvorming. Hoewel de meningen over de meeste thema's uiteenliepen, waren bijna alle behandelaren het er over eens dat TREAT de gedeelde besluitvorming ten goede kwam.

Ons doel in **hoofdstuk 6** was om deze gerapporteerde toename in gedeelde besluitvorming verder te onderzoeken. Gedeelde besluitvorming wordt door behandelaren en in richtlijnen aanbevolen als een belangrijk aspect in de behandeling van mensen met ernstige psychiatrische aandoeningen, maar tegelijkertijd zijn er verschillende studies die laten zien dat het niet altijd goed wordt toegepast. Een totaal van 187 patiënten, uit vier verschillende instellingen in Noord-Nederland, nam deel aan onze trial. Ze ontvingen standaardzorg in de eerste fase, werkten met TREAT in de tweede fase en ontvingen opnieuw standaardzorg in de derde fase van het onderzoek. De bevindingen van de kwalitatieve studie werden niet gerepliceerd door de bevinding uit de trial. Patiënten ervoeren zowel een hoge mate van gedeelde besluitvorming als een hoge mate van tevredenheid met de consultaties in alle fases van het onderzoek. Onze bevindingen zouden deels verklaard kunnen worden door de relatief lange gemiddelde ziekteduur van de deelnemende patiënten (gemiddeld 23 jaar), hierdoor bezitten ze vaak veel kennis over hun ziektebeeld en hebben ze over de jaren een sterke therapeutische relatie opgebouwd met hun behandelaar. Op dit moment zouden we TREAT niet aanbevelen met als enige doel om gedeelde besluitvorming te versterken voor mensen die FACT-zorg ontvangen. Het is de moeite waard om beslistools, zoals TREAT, verder te onderzoeken in andere GGZ-settings waar meer beslissingsambivalentie heerst.

TREAT lijkt dus niet de mate van gedeelde besluitvorming te verhogen, maar kan het beslissingsproces wel op andere manieren beïnvloeden. Het doel van **hoofdstuk 7** was het onderzoeken van het effect van TREAT op de klinische besluitvorming. Om dit te onderzoeken is er gebruik gemaakt van de CDRC- vragenlijst die is gevalideerd tijdens onze pilotstudie. Deze vragenlijst werd ingevuld door behandelaren om te onderzoeken welke van de mogelijke 23 zorgbehoeften er tijdens het behandelcontact besproken zijn en welke behandelbeslissing er vervolgens is genomen. In totaal hebben 27 behandelaren deelgenomen met 166 behandelcontacten verdeeld over de drie fases van de trial. In de eerste fase van het onderzoek werden 51.1% van alle geïdentificeerde zorgbehoeften besproken tijdens het behandelcontract. In de tweede fase gebruikmakend van

TREAT, nam het aantal geïdentificeerde zorgbehoeften dat besproken werden tijdens het behandelcontract significant toe naar 70.4%. In de laatste fase van het onderzoek nam het aantal geïdentificeerde zorgbehoeften dat besproken werd tijdens het behandelcontract weer significant af tot 55.6%. In de eerste fase van het onderzoek werd voor 18.3% van de besproken zorgbehoeften een evidence-based behandeling geïnitieerd. Dit nam significant toe in de TREAT-fase, waarbij voor 33.4% van de besproken zorgbehoeften een evidence-based behandeling werd geïnitieerd. In de derde fase nam het aantal geïnitieerde evidence-based behandelingen voor besproken zorgbehoeften weer significant af tot 19.3%. Tot slot kunnen we concluderen dat TREAT bemoedigende effecten laat zien op de discussie en integratie van ROM-resultaten en richtlijnimplementatie in de vorm van geïnitieerde evidence-based behandelingen in de dagelijkse behandelpraktijk van de psychosezorg.

In **hoofdstuk 8** reflecteren we op onze voornaamste bevindingen en plaatsen we deze in een bredere klinische context. In een wereld waarin we in rap tempo bewegen naar een nieuw digitaal tijdperk, begint nu ook de GGZ mee te bewegen met verschillende innovatieve technologische ontwikkelingen. TREAT is een voorbeeld van hoe technologie de manier kan veranderen van hoe we zorg verlenen. TREAT integreert patiëntgegevens op een innovatieve manier in de behandeling en maakt tevens op het juiste moment in de behandeling de relevante informatie uit richtlijnen en zorgstandaarden beschikbaar. Met een verdere doorontwikkeling van TREAT kan er een nieuw digitaal platform ontstaan waar verschillende vormen van digitale innovatie met elkaar verbonden kunnen worden. Het belangrijkste dat dit proefschrift heeft laten zien is dat beslissingsondersteuning van toegevoegde waarde kan zijn in de GGZ in het algemeen en specifiek in de psychosezorg.

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ABOUT THE AUTHOR

Lukas Roebroek was born in 1985 in Nijmegen and raised in Tilburg, the Netherlands. After finishing pre-university school (VWO) in 2004 at Koning Willem II college in Tilburg, he studied Psychology at Tilburg University. He developed an interest for research methodology and Social Psychology, for which he completed a minor. After completing his bachelor in Psychology, Lukas started the research oriented master of Youth Studies at Utrecht University. His master thesis: "The reciprocal relation between adolescents' school engagement and alcohol consumption, and the role of parental support", was published in *Prevention Science*. His thesis was also nominated for the Peter G. Swanborn price for best master thesis of the year at Utrecht University.



After completing his master, his initial attempts to pursue a PhD were turned down. He first worked as a researcher for the Verwey-Jonker Institute in Utrecht and as data analyst for Zimmer Biomet, before eventually being offered the chance to start a PhD project under the supervision of Prof. Stynke Castelein, Prof. Philippe Delespaul and dr. Jozanneke Bruins at Lentis Research. In the past four and a half years, Lukas and his colleagues, developed a clinical decision aid named TREAT. They also conducted a multicenter study to test TREAT in a clinical setting.

Currently, Lukas is working as a project manager for Akwa GGZ and P3NL. He is responsible for implementing the improvements as suggested by the Dutch National Health Care Institute for the treatment of psychotic illnesses and post-traumatic stress disorders. Some of these improvements are in line with the findings and recommendations from his PhD thesis. It is a great honor for him to be involved in realizing these improvements on a nationwide level.