

Ein Zweijahres Follow-Up zur Akzeptanz und Wirkung einer digitalisierten Urinkontrolle bei Drogenabhängigen

A two-year follow-up on the acceptance and impact of digitized urine testing among people with drug addiction

English translation of the German-language publication

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Abstract

Purpose The current follow-up study examines the long-term acceptance and impact of a digitized urine monitoring system two years after the already published initial study among 24 substitution patients who were still using the procedure.

Methods Twenty-four patients with drug addiction, all of whom had prior experience with direct observation during urine collection, participated. The mixed-methods study used multiple seven-point scale questions addressing technical handling, psychosocial effects, and concerns and problems associated with urine sample collection. Qualitative data were collected using guided expert interviews.

Results The system was widely accepted, with older and psychosocially disadvantaged individuals approaching the ratings of younger and less psychosocially disadvantaged individuals. Key findings included a paradigm shift through successful reassignment of responsibility to those who have the drug-related problem or wish to demonstrate freedom from drugs and manipulation independently. Increased self-efficacy and everyday coping, significant time savings for two-thirds of users, and a noticeable reduction in shame and psychological stress were reported. Digital monitoring remained process-enhancing in post-pandemic times and was recommended by most participants. Psychosocial effects and the therapeutic alliance improved compared with conventional direct observation.

Conclusion Overall, the two-year results indicate clear advantages over conventional urine testing, making digital urine testing a promising instrument in addiction therapy.

Introduction

Monitoring adherence is an essential part of the therapy for patients with drug addiction. The most commonly used matrix for this purpose is urine, the collection of which conventionally requires direct observation during urination (DO) to detect possible manipulations. In addiction treatment, adherence is an important factor with a high influence on therapy outcomes and treatment costs [1,2]. At the same time, conventional testing for drug abstinence has slightly negative effects on the therapeutic alliance and adherence [3,4]. Therefore, an alternative method, now well-established, has been developed in which only the intake of a urine marker substance needs to be verified [5,6,7,8]. DO ties up staff, and patients also have to accept time-consuming travels and processes, both on an outpatient and day-patient basis. The COVID-19 pandemic has definitively shown that new procedures are needed that can be carried out with as little direct contact between patients and control personnel as possible. To this end, the urine marking method has been further developed in recent years as a digital method (Ruma Digital-System (Pro)), in which patients orally ingest polyethylene glycols as a urine marker substance during a two-minute smartphone video recording [9]. The recording is asynchronously validated by the physician or a responsible person for tampering attempts during marker intake, and the patient can then independently send the subsequent urine sample to the relevant laboratory. The system was investigated in a previously published initial observational study [10]. In this study, patients could choose between conventional visual or digital urine monitoring. Digital monitoring was primarily chosen by younger, male patients with fewer psychosocial difficulties. Positive outcomes included reduced feelings of shame regarding urine monitoring, easier coping with daily life, and a high willingness to recommend the system. Two-thirds of users benefited from significant time savings, as travel and waiting times were eliminated. The system supported self-efficacy, was less psychologically stressful, and proved to be fully applicable in everyday clinical practice, even in pandemic situations.

The aims of this follow-up study are a) to investigate the long-term acceptance of digital urine testing and the psychosocial effects of its use in comparison with the patients' experiences, and b) to identify possible age-related differences in acceptance over time. The second aim is to explore explanations for why, in the initial observational study, a clientele that was on average younger than the control group opted for the digital procedure. To gain a deeper understanding, particularly of the intrapsychic and psychosocial effects of application, the quantitative analysis in the current follow-up study was supplemented by qualitative dimensions of patient experience and psychological impacts using guided interviews. Adherence (trust and therapeutic alliance), perceived stress, autonomy (including self-efficacy expectations), and motivation during digital monitoring were defined as overarching categories of subjective patient experience, based on a review of the existing dataset of ten guided interviews.

Method

The study protocol was submitted to and approved by the Ethics Committee of the Rhineland-Palatinate Medical Association.

Patients

The initial, multicenter study [10] was conducted at two Finnish and one German center. The German center continued to offer the Ruma Digital-System (Pro) to its patients after the study was completed. Of the original 39 patients at this center, 9 had left the institution. 24 of the remaining 30 patients continued to use the system and will be considered here. The study consisted exclusively of patients undergoing substitution therapy (6

women, 18 men). The mean age was 42.8 ± 9.7 years, with an age range of 23 to 59 years. For the quantitative analysis of age-related effects, the entire group was divided into two equally sized groups of $n=12$ each: "young" (34.9 ± 5.7 years) and "old" (50.7 ± 5.7 years). All patients had previously experienced direct observation by the therapeutic team during urine collection before switching to the digital system.

Quantitative and qualitative mixed-method design

Quantitative method

For the current study, a quantitative 2-year follow-up (time point T3) of the initial study [10] was first conducted. For T1 (immediately after the first application) and T2 data (after the 5th application = 8 to 12 weeks), only the results of the currently enrolled patients were considered. The questions were polarized endpoint-named, as in the initial study, and scaled from 1 to 7. Specifically:

- How easy do you find the app's structure and operation? (1 = very easy to understand, 7 = very difficult to understand)
- How sufficient was the maximum total video recording time of 120 seconds? (1 = perfectly sufficient, 7 = not at all sufficient)
- Have you become more familiar with the marker procedure (1 = has improved significantly, 7 = has not improved at all)?
- How nervous were you during marker intake? (1 = not nervous at all, 7 = very nervous)
- How worried were you about doing something wrong? (1 = no worries at all, 7 = very worried)
- How worried were you that a phone call might interrupt the video recording and the test could be marked as a failed attempt? (1 = no worries at all, 7 = very worried)
- How unpleasant is the unannounced urine test for you? (1 = not unpleasant at all, 7 = very unpleasant)
- Does the Ruma app change feelings of stigmatization or shame during urine tests? (1 = significantly less stigmatized, 7 = significantly more stigmatized)
- Does the Ruma app make it easier for you to manage your daily life compared to other urine tests? (1 = makes it much easier, 7 = makes it not easier at all)
- Does the Ruma app increase or decrease your trust in your doctor? (1 = significantly increased, 7 = significantly decreased)
- How likely are you to recommend the product to a friend who will also be undergoing a drug test? (1 = very likely, 7 = very unlikely)

Statistics of the quantitative analysis

The results from the three data collection points (T1 = after the first application, T2 = after the fifth application, T3 = after two years of application) are presented descriptively as mean value and standard deviation. The data were first checked for normal distribution using the Shapiro-Wilk test. Therefore, temporal changes were examined for significance using Friedman's non-parametric one-way ANOVA, and differences between the "young" and "old" groups at individual time points were analyzed using the two-sided t-test for independent samples. A significance level of $< 5\%$ was set. All statistical analyses were performed using the open-source software JASP (Jeffrey's Amazing Statistics Program).

Qualitative method

For the qualitative part of the study, expert interviews using a guideline were conducted with selected patients. Participants were divided into quintiles based on their total score from the quantitative analysis. From these quintiles, two participants were then selected for the qualitative analysis and invited to the

interviews. If participants were unwilling to participate or did not attend, the next person in the respective quintile was invited. The recorded interviews underwent qualitative content analysis, and categories were deductively derived from the resulting material. These categories were then inductively refined after the material was analyzed

Structure of the guided interview

For the guided interview, 12 questions were developed regarding the processing and experience of the procedure, which participants were encouraged to answer as freely as possible. Closed questions were deliberately avoided in the selection to allow for the broadest possible range of responses. The categorization was initially carried out deductively according to Mayring [11], with five overarching categories being formed by referring to the theoretical framework of the study. These were: 1. Adherence, 2. Shame and trust, 3. Self-efficacy, 4. Intrinsic and extrinsic motivation, 5. Significant changes in life domains.

The guided interviews took place approximately four months after the quantitative data was collected. One interview was scheduled per participant. The average interview time was approximately 25 minutes per person. Interviewees received €50 as compensation. The interviews were transcribed live using Cisco WebEx software and subsequently edited for transcription errors and artifacts (punctuation, spelling, background noise, dialect). Subsequently, the raw material was reviewed using the five overarching categories, and an initial evaluation and selection of relevant text passages was carried out. Following this, the categories were partially modified inductively, as new insights emerged from the data review. While the previously derived categories and associated questions sufficed for a differentiated assessment of the experience and processing of the control system, it was consistently evident across all participants that the content references were associative and thus transcended specific topics and questions. The categories of adherence, autonomy, motivation, and perceived stress were inductively derived (Table 1).

The transcripts were translated into a version that included only the relevant, coded passages. All transcripts were coded according to the final categories, considering units of meaning and individual sentences. Broad coding rules were established, which included, among other things, emotional experience and certain signal words. Subsequently, the coded excerpts were assigned super- and subcategories. Anchor examples can be found in the results section.

After complete coding of the transcript and assignment to subcategories, the sums of mentions of individual categories were calculated in a final step to obtain a descriptive quantitative overview of all categories of the guided interview.

3 Results

Adherence	Empowerment	Motivation	Experience of stress
Trust	Self-efficacy	Promotion of abstinence orientation	Emotional processing
Anonymity	Independence	Appreciation	Management of comorbidities
Threshold for falsification	Conditioning within the social environment	Acceptance	Integration into daily life/facility
Safety/control			

Table 1. Inductively derived categories.

Results

Quantitative analysis

Aspects regarding the technical handling of the procedure

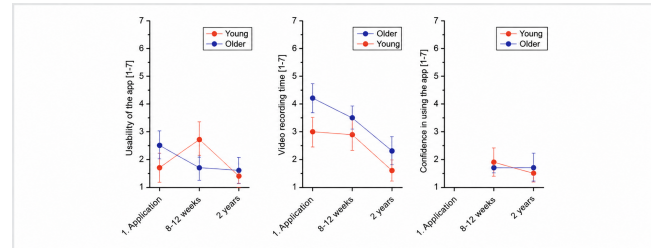


Figure 1. Time course of responses concerning the technical handling of Ruma Digital-System (Pro). Mean values $\pm$ SD.

Figure 1 shows the time courses of the investigated technical aspects for the two age groups. The general comprehensibility of Ruma Digital-System (Pro) was already high for the entire group during the first applications (T1 and T2), with mean values of 2.1 ± 1.7 and 2.2 ± 1.9 respectively, and tended to improve to 1.5 ± 1.2 at time T3.

There were no significant differences between the two age groups. Satisfaction with the prescribed maximum video recording time of 120 seconds for marker administration improved significantly at T3 compared to T1 and T2 ($p < 0.001$), with the younger patients consistently coping better. Overall, regardless of age group, handling of the procedure was already at a good level after the 5th application (1.8 ± 1.3) and improved slightly to 1.6 ± 1.4 at T3.

Aspects regarding concerns and problems with urine sample collection

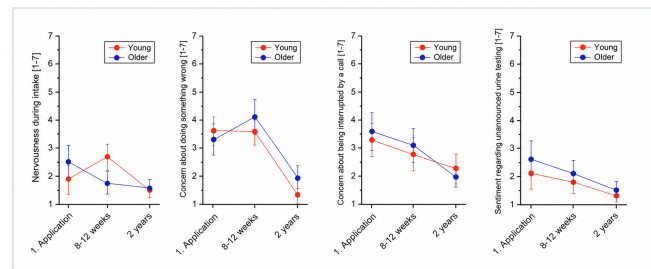


Figure 2. Time course of responses concerning worries and problems during urine sample collection. Mean values $\pm$ SD.

The time courses of the investigated aspects related to worries and problems during urine sample collection are shown in Fig. 2. Nervousness during marker administration and the worry of making a mistake improved significantly in T3 compared to T1 and T2 (Table 2).

The concern about making a mistake also decreased significantly at T3. The reduction in anxiety that a phone call would interrupt the video recording and thus result in a failed attempt was just short of statistical significance. The unannounced urine test was already perceived as slightly unpleasant at time point T2 (mean 2.4 ± 2.1) and tended to improve to 1.5 ± 0.9 at T3. The results showed no significant difference between the age groups.

Aspects regarding the psychosocial impact of the procedure

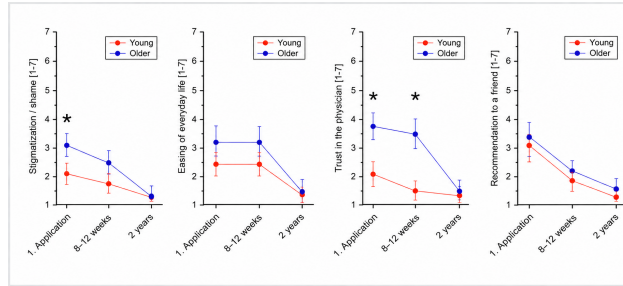


Figure 3. Time course of responses concerning psychosocial effects of the procedure. Mean values $\pm$ SD; * = significant difference between younger and older groups.

All four aspects showed a significant improvement from T1 to T3 (Table 3). Significant differences between the age groups were found for the feeling of reduced stigmatization and shame at T1 and for increased trust in the doctor at T1 and T2 (Fig. 3).

Qualitative analysis

Item	T1	T2	T3	p
Nervousness during marker intake	3.2 $\pm$ 2.0	3.1 $\pm$ 1.7	1.5 $\pm$ 0.9	< 0.001
Concern about doing something wrong	3.5 $\pm$ 1.7	3.9 $\pm$ 1.9	1.6 $\pm$ 1.2	< 0.001
Concern about call interruption	3.5 $\pm$ 2.1	3.0 $\pm$ 2.0	2.1 $\pm$ 1.5	= 0.084

Table 2. Mean values, standard deviations, and probability of error (p) for the time trend of nervousness and concerns during marker intake. T1 = immediately after first use; T2 = after 8–12 weeks; T3 = after 2 years.

Outcome	T1	T2	T3	p
Stigmatization	2.6 $\pm$ 1.1	2.1 $\pm$ 1.1	1.3 $\pm$ 0.5	< 0.001
Coping with daily life	3.4 $\pm$ 2.1	2.8 $\pm$ 1.5	1.5 $\pm$ 0.9	< 0.001
Trust in physician	3.0 $\pm$ 1.6	2.7 $\pm$ 1.6	1.5 $\pm$ 0.9	< 0.004
Recommendation	3.4 $\pm$ 2.1	2.0 $\pm$ 1.3	1.4 $\pm$ 0.8	< 0.001

Table 3. Mean values, standard deviations, and probability of error (p) for the time trend of psychosocial outcomes.

Adherence

The qualitative survey revealed a subjective improvement in adherence across all participants, with one exception who reported no change in adherence. In addition to increased trust, improvements regarding privacy protection (anonymity) and the perceived threshold for falsification were most frequently cited. The therapeutic alliance is perceived, among other things, as being based on mutual trust: "(...) there is greater trust in the medical assistants because they are no longer looking over my shoulder. I am less afraid of making mistakes; after all, Ruma is not a rapid test, but rather the actual test, the full test." Trust is sometimes even described in three dimensions: trust in the method and the practitioners, and trust in oneself – the latter also through greater autonomy: "My trust in him has increased. If anything comes up now, I want to speak to him right away. When it comes to relapses, became more open. Before, he almost had to whack me. It really takes a lot of pressure off." "There's more trust in the relationship, since he can have so much trust in me with this method. I'm going about it with more ease."; "You can put the feeling right next to the procedure and it is exactly the

same. So there is more self-determination and trust, yeah." Anonymity is repeatedly described as a particularly relevant factor for good adherence, with both the option of privately providing urine samples without observation and the associated visibility of visiting the clinic being mentioned, e.g., "It's generally unpleasant to come here. With me, nobody knows." and "It's already unpleasant when you have to pee and someone is standing in front of you. So, privacy is obviously much better with the Ruma (...)."

The fundamental need for control/security is brought into focus by patients, who on the one hand perceive the procedure as safer, but on the other hand also consider self-monitoring to be more secure against manipulation. This is also linked to emotional relief (see 3.2.4), for example: "I'm less anxious then. I can't cheat. Maybe it's a kind of self-monitoring, knowing: Okay, I have to hand in a mark."

Empowerment

Subcategories associated with empowerment included self-efficacy, independence, and conditioning with the environment. In the category of empowerment, seven interviewees showed an improvement on a subjective level. Contrary to initial expectations, aspects of self-efficacy expectations and classical and operant conditioning of abstinence evidence with the environment were not the main focus. Rather, participants emphasized in particular the advantage of independence, i.e., "doing it yourself," and only partly that this refers to the perception of the consciously abstinent self: "When you control yourself more, you are stricter, then you become so self-confident, yes, because you realize, I can do this and I am also the (...) adult, so sensible."

Some participants report that the increased autonomy and personal responsibility can also be experienced as problematic: "Unusual, in general. You're so focused on it, so fixated on it, that there's this kind of direct observation going on, and then suddenly it's gone. It can be quite unpleasant. Like: Wow, will this work out? I hope I don't make a mistake!"

Motivation

Direct positive effects on the motivation to provide proof of abstinence were reported by a minority of participants. Rather, it became apparent that adherence, and in particular a reduced experience of stress, promoted acceptance of the procedure and thus indirectly also motivational processes towards maintaining abstinence.

The motivation to maintain abstinence becomes apparent through various statements, clearly showing that increased subjective control/security in the course of independence and a higher abstinence orientation seem relevant: "My confidence is increased because one has a feeling of security." "I'm doing my best. Here, more initiative and independence are needed." Of further significance is the finding that several patients report experiencing increased motivation to abstain from additional substance use (e.g., cigarettes) through the Ruma procedure: "And also because I'm currently using something else, and it provides some additional motivation somehow to get off those damn things." Four participants reported an increased focus on abstinence, which may indicate increased intrinsic motivation, e.g., "It's so much easier to maintain abstinence through the process than the other way around (...)" or "Before, we didn't really discuss the urine tests, but we talk about the Ruma app."

Experience of stress

In line with the quantitative results, all participants experienced a perceived reduction in stress in at least one aspect. This is primarily due to the perceived emotional relief across numerous areas, but also to the ease with which the procedure can be integrated into daily life. It is described that the procedure

reduces shame (associated with emotional relief), and a distinction is often made between one's own shame and that of the monitoring staff, particularly in the case of opposite-sex staff. Stress inducing cognitions such as "If I knew I had to handle someone else's urine cup like, 10, 15, 20 times a day... forget about that little bit of glove. Then dripping it into the tester. I'm looking at it from their perspective, you know..." were eliminated by the procedure. The absence of commands and directive instructions is also perceived as emotionally relieving: "With the urine tests, everything is precisely dictated: 'Now (...) stand up straight' and things like that." A particular aspect within substitution practice is linked to the receipt of the substitutes: The perception of a strong, sudden craving among fellow patients before submitting their urine sample as a prerequisite for receiving the substitute would often be an overwhelming moment, as this frequently leads to discussions, loud shouts and demands on fellow patients to "speed up" in providing the urine sample. "I'm not so tied to a schedule. There are no shouts from the waiting room (from the other patients, author's note)." "We're already waiting! Can you pee now?" Emotional relief is perceived through the elimination of hectic, time-pressured supervised tests during peak hours and in overcrowded waiting rooms.

Further statements relating to stress reduction, besides the emotional relief, also point to the high degree of possible integration of the method into everyday life and the resulting ease of use. Statements such as "It integrated itself so well that it just became second nature, like drinking my morning coffee, for example" or "I'm less stressed; it's much faster here" suggest that efficiency and integration into daily life, along with expanding one's own options for action within the framework of control, contribute to further stress reduction.

One participant noted: "Now I'm independent, free to submit it whenever I want within 12 hours. There's no pressure, no obligation, so it's less stressful." The finding that some participants even experienced direct positive-valent affects when using the digital urine test is also interesting: "Definitely less unpleasant, more playful. I just put my phone down, scan the QR code, draw up the syringe like in a lab. It would even be best if you could do the analysis too."

Overall overview

Table 4 shows the categories and the total number of mentions by the patients.

Adherence	48	Fatigue	25	Motivation	12	Stress reduction	55
Increased confidence	16	Self-efficacy	1	Support for abstinence orientation	10 -2	Emotional relief	33 -1
Anonymity	15	Independence	19	Appreciation	2	Managing comorbidities	2
Lower barrier to falsification	10	Conditioning with the environment	5	Acceptance	2	Integrability into everyday life / convenience	21
Security /control	7						

Table 4. Summed category mentions after coding, paraphrasing, and reduction. Bold totals in the publication indicate overall mentions; negative values indicate deterioration.

Discussion

General

Of the 30 patients recorded in the studied facility over the entire two-year observation period, 80 percent are still using the Ruma Digital-System (Pro). The high long-term success rate can be explained, among other things, by the fact that the initial use of the digital system was voluntary and not randomized. In the original study, it was primarily younger men with less psychosocial stress who opted for digital urine testing and against direct observation. No differences were found between the two age groups in the current study with regard to technical aspects of use or concerns and problems with urine sample collection. However, the positive psychosocial effects during the initial usage phase were significantly lower in the older group. This suggests that the initially lower acceptance of digital monitoring among older patients is due more to lower expectations than to a fear of new methods and technologies. Long-term use, however, demonstrated the advantages of the digital system regardless of age: The feeling of shame associated with urine tests decreased, daily life became easier, and the elimination of travel and waiting times resulted in significant time savings. Older individuals and those initially more burdened also rated the system equally positively after two years. Apparently, the consistently positive experiences convinced previously hesitant users.

Furthermore, the long-term results show additional therapeutic and psychological benefits compared to direct observation during urine sample collection, which all patients had experienced before switching to digital monitoring. Firstly, the therapeutic alliance improved: Without direct observation during urine sample collection, patients felt more respected and approached the treatment team with greater trust. Many reported being able to speak more openly about problems or relapses, as the tests were no longer fraught with anxiety or shame. Secondly, there was a significant reduction in stress. Nervousness and embarrassment before the urine test decreased considerably – most participants perceived the test situation as a routine, relatively undemanding experience. This emotional relief is likely to increase their willingness to adhere to the therapy long-term.

Also significant is the increase in autonomy and personal responsibility. Those affected can participate in shaping the timing and procedure of the test process within a 12-hour period, thereby experiencing greater independence. This empowerment increased many patients' sense of self-efficacy – they realized they were actively contributing to therapy adherence. Some patients reported that this newfound freedom and the therapist's trust in their cooperation further strengthened their motivation to abstain. A positive reinforcement effect is emerging: Successful tests completed on their own increase confidence and commitment, which in turn promotes the maintenance of abstinence. Therefore, it is concluded that the digital system should be viewed as more than just a monitoring tool; it should be considered more of a therapeutic instrument.

Implementation in clinical practice

Several practical consequences can be derived from the findings. The digital monitoring system should be integrated into daily treatment practice as an option, wherever possible. Remote monitoring proved to be reliable and accepted over two years, so that it can largely replace the usual direct observation in substitution clinics. After brief training, the system was found to be intuitive to use, and attempts at manipulation could be reliably detected. For the facilities, this offers not only psychological advantages but also organizational relief: staff are freed from time-consuming monitoring, and tests can be scheduled more flexibly (urine tests no longer have to be carried out at fixed times). Furthermore, the procedure remains fully feasible in exceptional situations – such as pandemic-related contact restrictions – which increases security of care.

Furthermore, location-independent urine testing supports the therapeutic process with regard to content. By eliminating the need for direct observation, healthcare professionals can focus more on the treatment itself. The test results can be openly discussed: A negative test offers an opportunity for praise and reassurance, while

a positive result can be discussed constructively without blame. Thanks to the increased trust, patients are more cooperative and honest, which promotes solution-oriented dialogue. Last but not least, digital urine testing can serve as a follow-up measure. Continued voluntary use of the system after completion of inpatient therapy – as a kind of “low-threshold safety net” – could prolong periods of abstinence, as the basic need for orientation and control while maintaining abstinence is continued to be met [12]. Regular self-monitoring keeps the goal of abstinence in mind and allows for early detection of relapse, enabling swift intervention. Many patients have indicated their willingness to adopt this approach. Therefore, this telemedical procedure has a place not only during active treatment but also post-treatment as a stabilizing support tool.

In summary, the two-year results show that the digital monitoring system is not only scientifically effective but also practically feasible and provides multifaceted support for addiction therapy. The consistency of the findings between Study 1 and Study 2—from short-term acceptance to long-term psychosocial benefits—suggests that the method should be transferred from the research context into widespread practice. Implementing this in routine care can reduce traditional barriers (shame, mistrust, effort) to abstinence monitoring. This creates a more therapy-friendly environment for patients, which should result in better adherence and more stable abstinence [13]. In the long term, the use of telemedicine solutions could help improve treatment outcomes in addiction therapy, including through the implementation of more targeted contingency management [14,15] – a prospect that positively impacts both the patient experience and the efficiency of the healthcare system.

Limitations and outlook

As this was a follow-up study, no new patients could be recruited for it, consequently the statistical power is limited due to the small sample size. A randomized controlled follow-up study with a larger cohort should include health economic effects in addition to purely patient-related parameters. For example, comparing the number of fraud cases with the usual control system (direct observation) and the currently used Ruma Digital-System (Pro) in the inpatient setting provides concrete calculation bases for rehabilitation measures invested in vain.

Unlike the initial study, this is a monocentric study, meaning that local characteristics may have influenced the results. Further studies after the widespread implementation of the Ruma Digital-System (Pro) would be important in this regard.

One limitation of the Ruma Digital-System (Pro) is that it should only be used by those who accept it. However, this applies to all control procedures.

The improvements in adherence and stress cannot be definitively attributed to the monitoring procedure used, but could be partly due to general therapeutic or temporal effects. This also highlights a fundamental problem in the therapeutic setting, as the overall result can never be attributed to a single element of the treatment concept. In conclusion, it can be said that, even considering the limitations described, the Ruma Digital-System (Pro) represents a significant expansion of the spectrum of possible control methods and thus an expansion of the range of treatment options.

Conflict of interest

Author KB is a scientific adviser to Ruma GmbH. The other authors declare that they had no financial or personal relationships during the previous three years.

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