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Evaluating the first results of a need-driven digital mental health intervention for depression and anxiety; an exploratory study

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ABSTRACT

Background: Digital mental healthcare interventions (DMHIs) have been repeatedly mentioned as a possible solution for the growing demand for accessible treatment for patients suffering from common mental health problems, i.e. depression and anxiety disorders. However, structural implementation of DMHI is sparse and results on outcome seems inconclusive. To enrich the body of evidence, this paper compares a need-driven digital mental healthcare intervention (DMHI) for patients diagnosed with depression or anxiety disorders with traditional face-to-face treatment. The digital treatment is provided using a smartphone app which provides videoconferencing, chat, calendar- and registration functions.
Method: In a naturalistic retrospective cohort study patients who received DMHI are compared to patients who received traditional face-to-face treatment. Furthermore three illustrative cases were selected to demonstrate how personalization is expressed in individual treatments.
Results: The first results of the DMHI compare favorably with traditional face-to-face treatment, showing comparable satisfaction rates, equal effectiveness, and a significant decrease in treatment duration in weeks.
Conclusion: The DMHI has the potential to be as effective, but more efficient than traditional face-to-face treatment. Furthermore the digital treatment opens up options to fine-tune the frequency, duration, and content of care contacts to align with patients' individual situations and personal preferences.

Introduction

The global healthcare landscape is changing in response to the digital age; patients are becoming more outspoken and expect a more personalized and tailored healthcare experience which includes digital support tools, while professionals are facing increased administrative pressure combined with a growing demand for healthcare services in general. For mental health services the situation is not different, yet in this sector digital tools are frequently perceived as peripheral to the main treatment, which still largely takes place in a traditional, face-to-face setting. However, mental health problems are growing in incidence and severity, with the two most prominent ones, depression and anxiety disorders, together amounting to a significant loss of economic productivity, as well as reduced quality of life and even life expectancy.[1].

Digital mental healthcare interventions (DMHIs) have been repeatedly mentioned as a possible solution for the growing demand for accessible care for patients suffering from mental health problems. In the near future, DMHIs have great potential to revolutionize mental healthcare and to increase the efficiency and effectiveness of care. Beneficial effects on accessibility, treatment adherence, treatment outcomes and efficiency of fully digital execution of treatment compared to traditional execution of treatment are well established for common mental disorders, such as anxiety disorders and depression.[2–3] Preliminary evidence shows that even in cases of challenging psychiatric emergencies, videoconferencing proved to be suitable for high quality, decentralized mental health services[4].

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Despite their positive outcomes, so far, widespread adoption of technology as a central component of treatment execution and structural and sustainable implementation on large scale has not been successful.[5–6] Lipschitz et al.[7] suggest the reconsideration of several aspects to be able to close the existing research-to-practice gap. First, design processes must be driven by relevant stakeholder groups, whose input is necessary to create solutions that meet needs and are workable. They secondly suggest that common clinical preconceptions about what treatments should look like should be revised if new intervention paradigms are to be created successfully. Third, sustained adoption of the DMHI must be the goal of evaluation. Therefore, evaluation methods have to be chosen that are rapid and agile to adapt to iterative improvement of the intervention during the trial process.

Generally, healthcare delivery paradigms are based on professionals' *appraisal* of patients' healthcare needs (i.e., outsider perspective) rather than on patients' own *felt* difficulties and complaints in their functioning as a human being (i.e., insider perspective).[8] This seems to have resulted in a fragmented supply of healthcare, and an inefficient use of scarce resources[9]. A Dutch study has shown that need-driven approaches are appreciated by patients. They especially value being heard at their convenience and being seriously involved in the decision-making process of their treatment planning[10].

Finally, specific to the tool side of DMHIs, Huguet et al.[11] note that mobile apps "based on clinical best practice, that [meet] the most basic usability standards, that [are] evaluated scientifically, [have] a privacy policy, and [deal] with safety matters [have] the potential to remove barriers to care and alleviate suffering for a large number of people with depression at a modest cost". They additionally note that many existing apps fall short of these requirements and more work should be done to achieve them.

A need-driven DMHI for depression and anxiety disorders

DMHIs enable the therapist to provide therapeutic interventions into patients' living environment, in contrast to traditionally executed treatments that take place within the clinical environment of the mental healthcare organization.[12] This aspect improves the ecological validation of the evidence-based interventions. Furthermore, DMHIs enable to offer therapy in a need-driven fashion, where the 'need-for-contact' of the patient is the base for contact frequency, duration, and form (chatting or videoconferencing) with the therapist as opposed to weekly appointments on fixed times. This implies that digitally supported interventions for anxiety disorders and depression are offered in a personalized way, fitted into the daily life of patients and targeted as much as possible to the specific moments the client is in need of support. For example,when symptoms tend to worsen or when supervision or coaching is needed in executing therapeutic exercise, the therapist can support the patient in vivo in their personal environment (home, work, bus, etc.). In contrast, traditional face-to-face treatment sessions are largely planned at predetermined intervals (such as once a week) based on the agenda of the professional, with minimal regular contact between professional and patient in between therapy sessions, and no supervision or coaching of therapeutic exercises in the patient's personal environment.

Mental healthcare organization PsyQ and software developer Sense Health developed and implemented a completely digital, need-driven DMHI for patients with anxiety disorders and depression who are in need of specialized mental healthcare. This DMHI is developed in accordance with the suggestions and best practices from the literature mentioned above. Furthermore, it is based on multiple years of experience working with a variety of digital tools as an addition to traditional treatment, and the limitations of this approach. Finally, the DMHI is developed in close collaboration with therapists as well as (ex-) patients, and is based on evidence-based interventions for the treatment of anxiety disorders and unipolar depressive disorders.

The DMHI is enabled through specialized software called NiceDay (https://www.niceday.app/). It consists of a smartphone app aimed at the client, and a web-based dashboard aimed at the therapist. The software facilitates a need-driven DMHI by offering chat and video conferencing functionalities, as well as the possibility to record a diary, enter feelings, fill out thought records, and plan tasks and events. Typically, therapists working with the DMHI have separate timeslots dedicated to need-driven activities, which they use to check up on patients between sessions and to respond to their questions or concerns. The therapist is transparent about workdays and working hours. Agreements on response-time are made at the start of therapy to overcome the illusion of immediate availability or responsiveness.

The DMHI is provided completely online: from intake, treatment sessions until the termination of the treatment. Besides video conferencing sessions, the therapist monitors treatment-related activities of the patient in the app on a daily basis and responds when necessary. Therapists can also interact with the patient via the chat function, to build up a therapeutic alliance and enhance the treatment process and progress.

Goals and ambitions

In this exploratory naturalistic retrospective cohort study, our primary goal is to examine DMHI treatment effectiveness and efficiency. Furthermore, illustrate the characteristics and treatment processes of three patients that participated in the need-driven DMHI in a naturalistic setting.

By doing so, we hope to illustrate recommendations and best practices for therapists and mental healthcare organizations to further develop DMHI and promote successful implementation of digitally supported mental healthcare in their practice or organization.

Our research questions are:

1. What are the first results of the DMHI compared to treatment-as-usual in terms of efficiency and effectiveness?
2. How is DMHI (personalized mental healthcare respectively) expressed in three individual treatments cases?

Materials and methods

Design

This study was executed along the lines of the declaration of Helsinki. After patients' consent was obtained, administrative data was collected and stored for reimbursement purposes. Originally, the data from routine outcome monitoring was primarily used for clinical use and stored accordingly. Additionally, the stored data were aggregated for cohort study purposes and to guarantee the anonymity of individual patients. Aggregated administration data was then used to gain insights into participants' characteristics, type of mental illness, and treatment efficiency. Pre- and post-treatment test scores from routine outcome monitoring were used to analyze treatment effects.

Furthermore, qualitative data was obtained from the psychologists who worked in a digital treatment team to identify relevant patterns noticed in the day-to-day administration of need-driven DMHI's, as well as the personal differences in treatment progression. Manually logged data from the app was used to illustrate treatment activity and process in three cases.

Setting and participants

The study was performed using a population of patients treated for unipolar depression or anxiety in the Netherlands. The Netherlands has equal access to healthcare for all citizens through mandatory health insurance which is subsidized for lower income groups. The DMHI is financed under existing reimbursement schemes which made it accessible to all patients at no additional costs.

All patients diagnosed with depression and/or anxiety disorders as (main) diagnosis in the period January 2018 – October 2019 were included in the study. Typically, patients were referred by their general practitioner to PsyQ's specialized mental healthcare organization for assessment and treatment. This mental healthcare organization consists of regular treatment teams that provide traditionally executed evidence-based protocols within the premises of the mental healthcare organization, next to dedicated digital mental healthcare teams that provide fully digitally supported treatment as defined in section 1.1. At the time of data collection, the dedicated online teams consisted of five to six DMHI-trained psychologists each. Also, all of them were trained and experienced in evidence-based treatment interventions for depression and anxiety disorders. The psychologists were supervised by a clinical psychologist who was in charge of initial diagnosis and supervising treatment process and progress, as is the case in Dutch traditional mental healthcare. Any additional psychopharmaceutical treatment was provided and regulated by a psychiatrist or a trained and supervised nurse practitioner. Provided interventions were evidence-based methods such as cognitive-behavioral therapy (CBT), behavioral activation (BA), and interpersonal therapy (IPT). Treatment was performed within the app environment (registrations, planning and notifications of performed activities) and executed in a need-driven digital fashion, relying on video-calling and chatting for communication. Communication between psychologist and patient was both synchronous (video-calling) and a-synchronous (chatting, feedback on registrations, diary information, etc.) thereby facilitating a dynamic therapeutic alliance.

All diagnosed patients with depression or anxiety disorders were referred to the digital treatment teams, except when there was a serious indication to refer to a traditional face-to-face treatment instead. However, at the time the data for the study was collected, the digital treatment teams were rather small at the time of the study, most of the patients had to be referred to the traditional treatment teams due to restricted capacity. Also, at the time the data for the study was exported from the system, part of the patient group had not finished treatment yet. However, despite the limited data available and the naturalistic character of the study during the time period studied, all patients with data available were included. With respect to performance parameters, these are only based on patients who completed treatment.

To answer the second research question, three cases that completed the digital treatment from the total population of 196 patients, were selected manually. This selection is based on primary diagnosis, different treatment choices made by the patient and professional, and availability of sufficient outcome measures to measure treatment effect. The goal of this case selection is to illustrate the different possibilities DMHI encompasses compared to the traditional treatment. Cases are anonymized in terms of specific personal details to prevent matching to individual patients.

Instruments and statistics

For routine outcome monitoring of treatment effectiveness, the Outcome Questionnaire (OQ-45.2), a standardized self-report outcome measure, was used. The OQ-45.2 is designed for repeated measurement of patient progress during the treatment process[13]. It assesses problems relating to depression, anxiety and substance abuse and provides a total score and four sub scores: Symptom Distress (SD), Interpersonal relations (IR), Social Role (SR) and Anxiety and Somatic Distress (ASD). All 45 items of the questionnaire are scored on a 5-point Likert Scale, ranging from 0 (never) to 4 (almost always). Psychometric properties of the Dutch version of the OQ-45.2 are considered adequate. The reliable change index (RCI) indicating clinically significant change for the Dutch population is 14 for the total scale.[14] In this study, we do not pay special attention to the four sub scores. Treatment effectiveness is defined as the difference in scores on the OQ-45.2, between the start and end of treatment.

Patient satisfaction with treatment is routinely assessed around treatment termination with a short questionnaire (KLANT), scored on a 10-point Likert Scale, ranging from 1 (poor rating) to 10 (excellent rating).

Both questionnaires are offered by automated e-mails in the context of routine outcome monitoring.

The quantitative data of the treatment groups was statistically compared using chi-square tests and independent t-tests.

Privacy and GDPR compliance

Informed consent was obtained from all patients for service improvement and scientific validation purposes. For this study aggregated and/or anonymized data was used. The supportive software is developed according to the NEN 7510 and ISO 27001 standards for information security, which ensures a proper handling of sensitive personal data by the software. All personal information is processed according to national and European legislation for data protection.

Results

Cohort results

During the selected time period, the total number of patients referred for treatment is N = 10249. A total of N = 425 patients (4%) were referred for the DMHI treatment versus N = 9824 (96%) were referred for regular face-to-face treatment Table 1.

Equal percentages of our groups have completed their treatment at the time the data was extracted, i.e. N = 4053 (41%) of the regularly face-to-face treated patients versus N = 169 (40%) of the DMHI treated patients. The distribution of gender is comparable for both conditions; i.e. 68% of the digitally treated patients respectively 63% of the traditionally treated patients is female and 32% respectively 37% is male. The mean age at treatment onset of patients who received digital treatment is significantly lower (35.7 years (±12.0)) than the mean age of patients who received traditional treatment (40.9 years (±12.9)).

Of all patients who were treated digitally, 50% have a primary diagnosis of unipolar depressive disorder and 50% have an anxiety disorder. This distribution significantly differs from that of patients who received traditional face-to-face treatment. 67% of the latter group has a primary diagnosis of unipolar depressive disorder, and 33% is diagnosed with an anxiety disorder.

As mentioned in the methods section not all patients had already terminated treatment at the time data was exported. During data export around 40% of the digitally treated patients and 41% of the regularly face-to-face treated patients had completed treatment. Results on outcome parameters, depicted in Table 2, are thus based on the patients who have completed treatment at that time.

On average, DMHI treated patients have statistically non-significant more treatment sessions with their therapist (12.9

Table 1
Baseline characteristics, primary diagnosis and severity of symptoms of patients who received digital treatment and patients who received traditional face-to-face treatment.

	Digital treatment		Traditional face-to-face treatment		
	N	%	N	%	*p*-value
# patients referred for treatment	425	100	9824	100	
# patients who completed treatment	169	40	4053	41	
Gender					.079[a]
Male	137	32	3595	37	
Female	288	68	6229	63	
Age at treatment onset (MEAN ± SD)	35.7 ± 12.0		40.9 ± 12.9		<.001[b]
Primary diagnosis					<.001[c]
Unipolar depressive disorder	212	50	6580	67	
Anxiety disorder	213	50	3176	33	
OQ-45.2 score at treatment onset (n;MEAN ± SD)[d]	296	90 ± 23.8	3947	91.6 ± 21.7	.804[e]

[a] Based on the chi-square test.
[b] Based on the Independent-Samples Mann-Whitney U Test.
[c] Based on the chi-square test.
[d] Not all data were available for all patients due to non-response on the routine outcome monitoring measurement.
[e] Based on the Independent-Samples Mann-Whitney U Test.

Table 2
Performance on relevant parameters of patients who completed treatment before data export.

	Digital treatment		Traditional face-to-face treatment		
	n[a]	Mean ± SD	n[a]	Mean ± SD	*p*-value[b]
Treatment duration (in weeks)	113	24.2 ± 13.8	3549	31.9 ± 17.4	<0.001
Number of treatment sessions	91	12.9 ± 11.0	2724	11.1 ± 11.1	0.601
Total time spent on treatment (in minutes)	91	486.0 ± 440.0	3033	513.4 ± 568.1	0.612
OQ-45.2 difference score	25	32.4 ± 33.5	231	29.6 ± 25.7	0.609
Patient satisfaction[a]	23	8.5 ± 1.7	295	8.2 ± 2.0	0.069

[a] Based on the patient group that already completed treatment at the time data was exported: n = 169 of the patients who received digital treatment and n = 4053 of the patients who received traditional face-to-face treatment; not all data was available for all patients due to missing registrations in the electronic patient record or due to non-response on the routine outcome monitoring measurement.
[b] Tested with independent *t*-test.

sessions) compared to the traditionally treated patients (11.1 sessions), but treatment duration and total time spent on treatment by the therapist is lower. While mean treatment duration of the group that was digitally treated is less than half a year (24.2 weeks), treatment duration of the traditionally treated group is longer than half a year (31.9 weeks). Treatment duration is the only outcome variable that tests significantly on the *t*-test for independent groups (p <.001), all other performance parameters tested statistically non-significant. Total time spent on treatment is also non-significantly lower for the digitally treated group (486.0 min) compared to the traditionally treated group (513.4 min). There are no statistically significant differences between both groups on severity of symptoms. The treatment onset score on the OQ-45.2 of the digitally treated group is 90.8 compared to the onset score of the traditionally treated group of 91.6. Also, the treatment effectiveness is comparable with a mean decline of 32.4 points of the digitally treated group and a mean decline of 29.6 points of the traditionally treated group. Both patient groups are statistically equally satisfied with the received treatment with a mean score of 8.5 for the digital treatment compared to 8.2 for the traditional treatment. Detailed statistics are described in Table 2 below.

Case results

To gain insight in DMHI-treatment characteristics for personalized mental health treatment (e.g., the different interaction patterns between therapist and patients and sharing of registration possibilities) and individual treatment progress patterns for patients we narrowed above mentioned results down to individual levels.

Three illustrative cases were selected that could be informative to therapists seeking to adopt DMHIs into their treatments. Below, we will summarize the progression per case using a timeline as a visual aid. For privacy reasons, any diary entries or event registrations are referred to only in general terms, and are not presented visually.

Patient A

Patient A was diagnosed with a panic disorder. Log data depicted in Fig. 1a show a treatment progression which is initially similar to a regularly planned treatment, with near-weekly sessions over a period of seven months. It's interesting to note however that the duration of sessions reduces over time, from roughly 45 min per session in the first weeks, to around 30 min towards the end of the treatment. According to the therapist, for digital treatments the trend of more frequent and longer treatment session in the first part of therapy and less frequent and shorter sessions towards the end occurs regularly.

Two months into the treatment, the patient starts logging emotion scores several times per week, focusing mainly on the registration of feelings of tension. Sessions with the therapist focus on interoceptive exposure to extinguish dysfunctional feelings of anxiety, which proved to be effective for this patient. Fig. 1b depicts registered feelings of motivation and happiness (more positive emotions) towards the conclusion of treatment as well as the significant reduction in symptoms (reporting less tension) as signified by the reduced OQ-45 score.

Patient B

Patient B was diagnosed with a first episode of a moderate-major depressive disorder. Results in Fig. 2 depict treatment

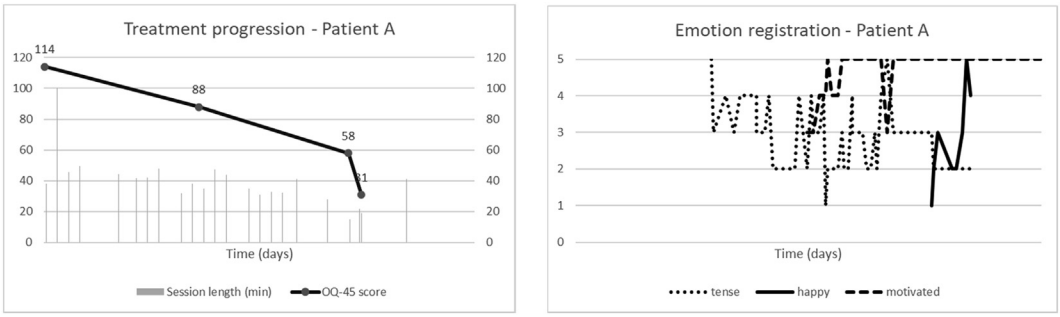

Fig. 1. a and b: Treatment progression (patient A).

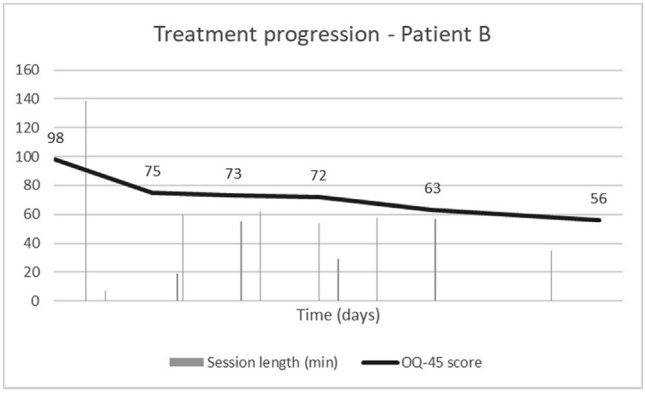

Fig. 2. Treatment progression (patient B).

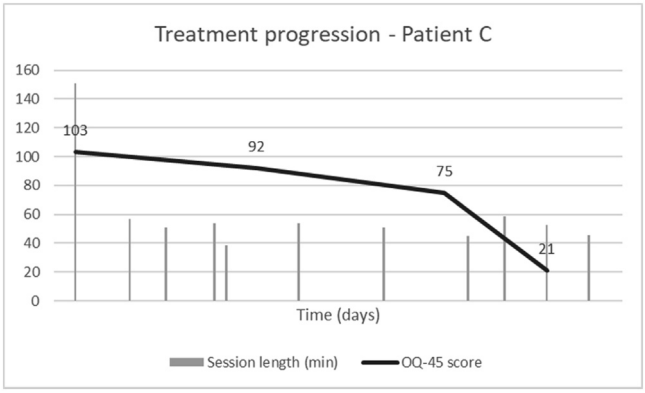

Fig. 3. Treatment progression (patient C).

progression which consists of intermittent videoconferencing contact with the therapist through somewhat longer sessions – almost two hours for the first session, followed by sessions of an hour at random intervals, over a period of six months.

Treatment sessions with this patient are held in the evening, since the patient has a full-time job. Short chat communications (synchronous communication) and chats (a-synchronous communication) are held during working time, when needed and possible (dynamic therapeutic alliance).

Activation and interpersonal therapy are the primary interventions used during treatment. The patient focuses less on registering emotions or diaries (as is commonly seen in the other two cases), and more on planning activities which make them feel happy, good, or otherwise engaged with people. Examples are visiting family and friends, going to the gym, and walking the dog. Typically, after finishing the activities the app generates positive feedback (well done) with invitation to perform the activation again at later moment in the week.

Patient C

Patient C was diagnosed with a recurrent episode of moderate major depressive disorder. The results depicted in Fig. 3 initially show a similar treatment progression as patient B; a longer initial session followed by intermittent shorter sessions and sparse chat contact, over a period of three months.

The patient's mood scores are shown to fluctuate during treatment, though overall OQ-45 scores decline significantly (103 versus 21).

According to the therapist, this patient prefers to use the diary function and mood registration function (a-synchronic communication). This facilitates him to express his emotions rather than retrospectively verbally express them during the video-conferencing sessions (synchronic communication).

With the help of registration of thought patterns in the app, the patient is able to understand the association between emotions, behavior and consequences that leads to relief of symptoms. The app-support facilitates insight in mental status for patients and gives opportunity for self-reflection.

Discussion

The aim of our study was to evaluate the first results of the DMHI regarding to effectiveness, efficiency and patients satisfaction and additionally gain insights in the potential beneficial effects as compared to traditional face-to-face treatment.

Regarding comparison of the DMHI-treatment to treatment-as-usual in terms of efficiency and effectiveness, the results of this naturalistic retrospective cohort study provide first indications that digital treatment, in our situation DMHI with Niceday-app support, has the potential to be as effective as traditional face-to-face treatment. Moreover, our preliminary results of routine outcome monitoring suggest that it could possibly be more efficient. In the studied patient cohort we find that DMHI treated patients on average have statistically insignificantly more treatment contacts with their therapist, while the total time (in minutes) spent on treatment is less compared to patients who received treatment as usual. Total treatment time (in weeks), however, is statistically significant less for DMHI treated patients compared to patients who received treatment as usual. Looking at individual treatment progressions, we receive indications that the number of contacts, length of treatment contacts and the digital functionalities used to support the treatment are likely to vary for different patient types. This is different to the traditional face-to-face treatment, where sessions are planned in a fixed interval.

Regarding how the DMHI is expressed in individual clinical cases and how the above discussed results relate our preliminary

results are promising. The results demonstrate that the DMHI offered various opportunities for personalized of mental health treatment such as:

(1) Flexible duration and frequency of interactions; since the planned sessions and patient-therapist contact in-between the planned sessions are based on the situation and need of the patient, some patients prefer having relatively stable contact moments, such as every week. Others prefer to have sessions be more 'as-needed', usually in response to a specific event or feeling they were experiencing. Overall, according to earlier studies on optimal treatment duration,[15–16] the optimal therapist-patient contact time can vary significantly based on differences between individual patients.

(2) The digital communication tool offers a number of functionalities that are used by the patient and psychologist in accordance to what is needed for the treatment and what works for the individual patient. For instance, one patient shows to benefit more from behavior activation, and thus uses mainly the event planning features, while another benefits more from the reflection offered by the feelings diary.

(3) Flexibility in mode of communication; while the patients in the studied cohort use primarily video contacts with intermittent chat messaging, in other patient groups where patient anonymity is a desired factor, chatting is a much larger component of the treatment.

Compared to the traditional face-to-face treatment, DMHI holds several potential benefits for patients, therapists and the organizations implementing this treatment form based on the assumption that results found in this primary study can be confirmed by results of more thorough scientific studies. Within digital treatment, there is no need for patients or therapists to meet within the premises of the healthcare organization, which saves travel time and costs. Therapists are able to treat patients from any location that provides stable internet connection and enough privacy, even from home. This offers flexibility in working place, but also working times, since treatment sessions do not necessarily have to take place during office hours. Future research assessing cost-utility of this treatment method compared to regular face to face treatment is needed to confirm the expected beneficial effects on societal costs.

Similar to traditional face-to-face treatments, but more apparent through the use/functionality of the app, patients have to be motivated to work on their problems in daily life. Thus, motivation and readiness to take the necessary steps to work on the symptoms is an inevitable topic of discussion when registration in the app does not take place as agreed. This could possibly lead to a quicker termination of treatment when a patient seems to be not ready for treatment. Since this possibility is not investigated explicitly in this cohort study, it should be investigated and verified in future research.

The personalized approach enables the therapist to differently structure the treatment course according to the situation and needs of the individual patient. Based on evidence-based techniques, this approach appears to be at least equally effective as the traditional way when taking outcome scores as a measure. The technology offers different components, and their usage varies per patient. This is likely because different emotions are relevant to different people, and some people are more inclined to plan events while others prefer filling out mood diaries or thought records. Duration of treatment sessions and frequency of sessions per time interval seem to decline over time (more intensive treatment early, more efficient sessions later).

Therapists evaluate working with the DMHI as positive; a reason for this may be that therapists receive courses in providing online CBT/ BA/ IPT, and that they are involved in research projects regarding the (cost)effectiveness of the DMHI, predictors for therapy success, quality of the online working alliance and extension of the therapist's reach. The online platform also makes it easy for therapists to share their experiences with colleagues, and to gain insights that make treatments more data-driven. Overall, the therapists experienced an extension of their reach – being able to communicate with the patient in their natural (home) environment and facilitate transfer of learned behavior to the patient's private environment.

Finally, the digital aspect of the treatment is not seen as a shortcoming by either patients or therapists, and treatment adherence (measured as the rate of patients that completed treatment) is similar to the traditional group. A possible explanation for this can be found in a recent article studying the success and failure of digital interventions[17], which denotes "undermined face-to-face communication" as a factor which leads to failed digital interventions. In this particular DMHI, the use of video calling ensures that face-to-face communication still takes place despite the "online" characteristic of the treatment. This also has a positive effect on the rapport built between the patient and therapist, although this is not formally investigated in this study.

Limitations

While the need-driven digital treatment could have advantages for patients and therapists, they are likely to be confronted with unfamiliar aspects they have to get used to. For patients who continuously show signs of avoidance (repeatedly last-minute cancelling of treatment sessions, unable to get motivated to actively work on problems) this kind of treatment would probably be counterproductive. While patients appreciate the direct connection with the therapist through the app, therapists must be aware and transparent that this direct line is timely and should not result in dependency neither from the therapeutic contact nor from the app.

Data used for this study was automatically generated data for reimbursement purposes and routine outcome monitoring. The study method lacks proper control of possible factors that could have influenced results. This may explain the large standard deviations seen in the results. The population for this study reflects the heterogeneous group of patients requiring care, with a wide variation in severity of complaints and need for care. This limitation together with the early phase in the implementation process of the new treatment way limits the certainty of generalizability of these preliminary results. In the early implementation phase, we recognize that therapists (most of them worked in the traditional manner before) need time to get used to the full potential of this new treatment way. They have to learn how to integrate the app properly in the treatment process and how to plan treatment sessions need-driven and integrate the registered data in the app in the treatment. Finally, therapists have to adapt to the new and differing information this kind of treatment provides, such as getting used to communicating with and seeing the patient in his/her private home environment.

We also found that there were statistically significant differences in the mean age at treatment onset, with DMHI treated patients being younger than regularly treated patients and that more DMHI treated patients suffered from anxiety disorder (over depression) compared to regularly treated patients. Similar to the above mentioned, we are not able to conclude in this phase whether these differences are future-proof or also the result of the method and timing of the study.

Apart from this, in this early phase of implementation there are no best practice guidelines when it comes to finding the right way to inform and motivate patients to accept this type of treatment. Patients expect to be treated in a traditional way, face to face. Most

of the patients are initially hesitant when the prospect of a digital treatment was offered to them. This can been seen as indicative of a learning curve for therapists as well as patients. Additionally, due to the restricted professional capacity of the digital working team at the time of data collection, the number of patients treated is rather small compared to the traditional group with corresponding limitations in data. Regularly less than 40% of treated patients have a completed routine outcome monitoring set with completed measurement at the start of the treatment and completed measurement at the end of the treatment[18]. This is even lower for the cohort group studied for this paper. The high non-response rate on the routine outcome measurement could bias the study results. Repetition of the study in a later stage with a larger dataset is necessary to verify generalizability of the preliminary results reported in this study.

The case results were formed based on cases that were selected as interesting or informative by the therapists who performed the DMHI, and they should not be taken as representative for all patients (nor were they intended to be).

By changing the delivery concept from schedule-driven treatment to need-driven, consumer leadership seems to arise naturally in the treatment process. While research on the effect of consumer leadership is limited until now, benefits have been demonstrated on innovation, accountability, quality of care and the public's perception of the mental healthcare organization.[19] It is likely that this form of care will not work for all types of patients, and will also not be practical for all types of therapists. Future scientific work has to be done to investigate which patient groups will benefit from this kind of treatment concerning to diagnosis, cultural and intellectual factors etc.

Finally, therapeutic alliance is an important common factor in mental health treatment outcome. When replacing traditional face-to-face treatment with video calling, the question arises whether therapeutic alliance can be established and maintained to the same degree as the face-to-face situation. The quality of the therapeutic alliance was not included in this study for obvious reasons.

Conclusion and future perspectives

The goal of the study presented in this paper is to evaluate the first results of the digital treatment of anxiety and/or depression in a clinical outpatient setting and additionally gain insights in the potential beneficial effects as compared to traditional face-to-face treatment.

In summary, DMHI treated patients show a significant decrease in symptoms after treatment, which is comparable to traditional (face-to-face) treatments. DMHI treatment is thus as effective as evidence-based treatment for depression and anxiety disorders. Future research should differentiate for disorder specific symptoms reductions for depression and anxiety disorders rather than the more general outcome questionnaire used in this study. Treatment time in weeks is significantly shorter by six weeks on average, though the number of minutes and sessions do not differ significantly between both groups.

When focusing on DMHI-treatment possibilities, a crucial area of study is concerned with the application positioning of this treatment compared to other treatment types and for other diagnoses; in essence, the DMHI has the potential to be transdiagnostic. The components behavioral activation, cognitive restructuring, working with planners and reminders, keeping a diary, assessment and evaluating using tracking and trackers are all transdiagnostic and can be applied to a variety of mental disorders beyond unipolar depression and anxiety disorders. Moreover, the modular design of the DMHI allows for specific modules to be developed to provide better support for certain treatment techniques, such as Eye Movement Desensitization and Rescripting (EMDR).

Patient satisfaction is positive for both groups. Therapeutic alliance is an important common factor in mental health treatment outcome and patient satisfaction. When replacing traditional face-to-face treatment with video calling, the question arises whether therapeutic alliance can be established and maintained to the same degree as the face-to-face situation. A review by Lopez et al.[20] shows that a common finding across different studies of different types of digital mental health care is that the viewpoint on the quality of the therapeutic alliance differs between patients and therapists. While patients report strong alliance and satisfaction with digital mental health care, therapists are more worried about the impact of online treatment on their relationship with the patient. We did not address this aspect in the present study. More research is needed to address the influence the digitalization of treatment delivery on therapeutic alliance and the consequences for therapy effect and relapse prevention in future research.

On an individual case basis, the DMHI seems to offer more opportunities for personalized treatment, varying session frequency and length according to need-driven practice, and offering the patient different tools for registration and behavioral activation based on their personal preference. However, more research is needed to determine whether these results are representative for larger patient groups. Such research is already being performed for PTSD and trauma related symptoms, building on earlier work for these patient groups[21,22].

Digital treatment has the potential to innovate mental health service delivery in several ways and provide solutions for gaps of traditional face-to-face mental health care:

1. The digital aspect of the DMHI seems to be well received by therapists as well as patients; therapists appreciate the new ways of working it opens up, while patients appreciate the possibility of integrating their treatment more easily into their daily lives and activities.
2. The need-based aspect of the DMHI implies that treatment is personalized according to the specific needs and situation of the individual patient instead of a one-size fits all manner of providing care. Different steps in the treatment process, the provision of relevant information and the choice for the best suitable intervention can be adapted to the individual patient and his/her specific situation.
3. By facilitating on-time registration and monitoring of relevant aspects related to mental health problems, professionals have access to more frequent, accurate and objective information compared to a recall of the patients' memory of certain events or feelings during a therapy session days or weeks later.
4. On-time registration and monitoring can provide a direct motive for a treatment session, as well as present topics to discuss during such a session. Within this type of treatment, we facilitate patients to be able to adhere to the specific plans that were agreed with the professional to work on treatment goals.

As we discussed in the previous chapter, we expect that these results might be limited due to the relative novelty of this DMHI, and the early stages of the implementation process. Nonetheless, we feel that they present an interesting starting point for future research, which could focus on establishing a better quantitative comparison of this form of treatment to traditional treatment forms, or examining more closely the effects of different personalization strategies (as illustrated in the case descriptions in 3.2). In light of the former, a randomized controlled trial (RCT) focusing on clinical effectiveness is currently being prepared as a follow-up to this preliminary study.

CRediT authorship contribution statement

Mirjam van Orden: Conceptualization, Methodology, Formal analysis, Data curation, Writing – original draft. **Jan C. Kraaijeveld:** Conceptualization, Methodology, Visualization, Writing – original draft. **Annet T. Spijker:** Supervision, Writing – review & editing. **Annemiek V. Silven:** Methodology, Writing – review & editing. **Tobias N. Bonten:** Methodology, Writing – review & editing. **Niels H. Chavannes:** Supervision. **Annemiek van Dijke:** Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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