The effectiveness puzzle of eHealth

What is the added value of online interventions for the treatment of aggression in outpatients in forensic care?

Dear client,

Would you like to participate in a study? The study is called: "The effectiveness puzzle of eHealth". On the pages below there is a lot of information. This information is about the purpose of the study and what you will be doing. That may be a lot of information to read. And difficult. That's why we've made a short summary below. This contains point by point what this study is about.

Why are we doing this study?

- Maybe you've made a module on your computer or phone.
- In such a module you follow lessons about a certain subject. You choose these with your practitioner.
- Such modules have been around for a very long time. But they are not used that much.
- We are going to investigate whether such modules help you and other patients during treatment.

What will you do?

- You will be placed in group 1 or group 2.
- Group 1 will work with the module Aggression. This is 10 lessons (1 lesson per week).
- One lesson takes about 30 minutes.
- Group 2 continues with their own treatment, without the module.
- The 2 groups complete a pair of questionnaires 4 times. This takes 15 minutes.
- The study lasts 26 weeks, but you don't have to do something every day.

Do you want to participate?

- You can decide whether you want to participate.
- If you participate you will receive a VVV voucher of 10 euros if you are halfway through the study.
- When you are finished you will get another voucher of 10 euro.
- If you do not want to participate it will have no effect on your treatment or course.
- If you have started the research you can always stop. Without any reason.
- If you participate, you will be told later which group you belong to: the group with the online module or the group without the online module.
- Your therapist or supervisor will tell you in which group you belong.

What will we do with your data?

- During the research we will use your personal data. These are personal data. We will make sure that this information is not disclosed. We will also store your data without your name being mentioned.
- Your data is stored on a secure disk on the computer. This disk is protected by a code.
- After the research is finished we keep the data for 15 years. After that they will be deleted.

More information?

- If you have any questions you can contact the researchers. You can find their email address in Appendix A.
- If you want to participate, you can sign the form in Appendix B.

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Introduction

We kindly ask you to participate in a scientific study entitled: "The effectiveness puzzle of eHealth". It is up to you whether you want to participate. Before you make your decision, it is important to know more about the study. Please read this information letter carefully. If you want, you can discuss it with your care provider or other people.

Do you still have questions after reading the information? If so, please contact the researcher Lisa Klein Haneveld (l.kleinhaneveld@transfore.nl). See also Appendix A.

Purpose of the study

During treatment, online modules are often used, like the ones from Minddistrict. This is also called eMental Health or EMH. In such modules you go through various lessons about a subject or treatment goal that you have chosen together with your caregiver. During the lessons you read about the subject, watch videos and answer questions. Your caregiver can also respond to your questions and answers. This gives you the opportunity to work on your goals independently and at your own pace (at home), while your healthcare provider remains available online to support and help you.

Despite the fact that such online modules have been around for 10 years within forensic care, they are used less than expected. Also, it has never been investigated whether they make the treatment better. Therefore, in this study we want to know if these modules can help you and other patients during treatment.

If you participate in the study, you will be compensated for your participation with a total of 20 euros, via a VVV voucher. This compensation will be given in two parts: 10 euros halfway through the study and 10 euros at the end of the study, when all questionnaires have been completed. This compensation is for both the intervention group and the control group.

How is the study carried out?

To investigate whether online modules have added value, we will conduct a randomized controlled trial: an RCT. This means that we will randomly, i.e. based on chance, divide all patients who want to participate in the study into two groups. One group is the ''intervention group''. This group will go through a Minddistrict module, as a supplement to the normal treatment. The other group is the ''control group''. This group will follow the normal treatment, without Minddistrict. We will assign you to one of these groups without looking at your name or your data. So we don't know yet in which group you will end up. You have a 50% chance of ending up in each group.

Possibility 1: the intervention group with Minddistrict

If you're assigned to the ''intervention group'', you'll start working with the 'Aggression' module in Minddistrict during your treatment. If you are in this group, your therapist will give you more information about the module and will show you what it looks like. It consists of 10 lessons about recognizing and dealing with aggressive feelings. The intention is that you complete one lesson each week. So it takes about ten weeks to complete the module 'Aggression'. You will work on the module independently, but will discuss it with your therapist.

You will also complete three short questionnaires four times during the study. You will do this (1) when you start the module, (2) when you are halfway through, (3) when you have finished the module, and (4) two weeks after you have finished (follow-up). The questionnaires can be completed via the online program Qualtrics.

Possibility 2: the control group

If you are assigned to the ''control group'' you will receive your normal treatment. You don't have to start with a module of Minddistrict. We do ask you to complete the three short questionnaires online four times during the study. We will remind you and your caregiver to do that. When the study is over, you can start following the module. If you are included in the control group, you will also receive a reimbursement of 20 euros.

How long will I be involved in this study?

The study lasts 26 weeks, but you do not have to do anything every day. Completing the three questionnaires takes about 5 minutes. So during the whole study you will spend a total of 20 minutes on the questionnaires. If you are in the Minddistrict group we expect you to spend about 30 minutes a week on a module.

Participation

Participation is completely voluntary. You decide for yourself if you want to participate. If you choose not to participate in this study there will be no negative consequences for your treatment. It is good to know that if you do want to participate, you can stop the study at any time. Even if you have already started. You do not have to give a reason for doing so. This also has no consequences for your treatment. You will receive the same treatment as you would otherwise.

It is important to know that if you want to participate in the study you have to say ''yes'' to both possibilities: participation in the Minddistrict group or participation in the control group. So think carefully if you would like to participate in both groups.

When you participate, we will record your name and randomly assign you to a group. Your caregiver or supervisor will tell you in which group you have been assigned. In the following weeks, you will start with the Aggression module or continue with your regular treatment. During this time, you will be reminded by your health care provider or counselor to complete the lessons from the module and occasionally complete short questionnaires online.

Confidentiality

Some information about you will be used and kept for this study. This includes data such as your signed consent form, your date of birth and data about your (mental) health. We will also look at the number of lessons you have completed, but not at what you have filled in exactly. Only you and your practitioner can see that. We also see your answers to the online questionnaires in Qualtrics.

All this data is treated confidentially. We store everything anonymously, which means that your name will not be linked to your data. Also, the data will not be passed on to others, except for people who are directly involved in the study. These are the researchers listed at the bottom of this letter, and possibly students who come to do an internship as part of their training in this research. To protect your privacy, your data will be coded instead of your name. Your name and other data that can directly identify you are therefore omitted. Only the key to the code can be used to retrieve data. The key to the code remains safely stored at the local research institute and the University of Twente. The data sent to the researchers contain only the code and no names or other data that can identify individuals. Also in reports and publications about the research the data cannot be traced back to you as a person. This means that all data we store are not linked to your name.

The collection of all this data is necessary to answer the questions posed in this study. That is why we ask for your permission to use your data via the consent form (see Appendix B).

With your data we hope to contribute to the improvement of mental health care.

Data retention period

Your data will be stored on the encrypted research servers of the University of Twente for 15 years. After this period the data will be destroyed.

More information about your security and rights with respect to data processing

The METC Oost-Nederland has granted exemption from the obligation to take out insurance for this research. The reason for this is that the committee is of the opinion that this research is by its nature without risk for the participants.

For general information about your rights with regard to the processing of your personal data, please consult the website of the Authority for the Protection of Personal Data or the website of the Dimence Group: https://www.dimencegroep.nl/kwaliteit-veiligheid.

If you have questions or complaints about the processing of your personal data, we recommend that you first contact the researchers (see the contact details in Appendix A) or the Scientific Research Committee (onderzoek@dimencegroep.nl). You can also contact someone who is not involved in the research but who can answer your questions (see Appendix A). In addition, you can contact the Data Protection Officer of the Dimence Group (see Appendix A) or the Personal Data Authority.

Is there anything else you would like to know?

If you decide to participate in this study, during our first appointment we will ask you to sign and date the consent form. The researcher will agree with you and your clinician how that consent form will be given: in person, by mail or verbally.
We hope you will want to participate in this important study! If you have any questions about the study, please feel free to contact the researchers (see Appendix A).

Kind regards,
Lisa Klein Haneveld, MSc / l.kleinhaneveld@transfore.nl & Dr. Hanneke Kip

Appendix

A: Contact details
B: Consent form

Appendix A: Contact details.

Researcher:
Lisa Klein Haneveld, MSc
E-mail: l.kleinhaneveld@transfore.nl T
Phone number: 0570-604455
Monday through Thursday

Principal Investigator:
Dr. Hanneke Kip
Phone number: 0570-604455
Monday through Friday

Independent advisor:
Dr. Lieke Christenhusz
E-mail: l.christenhusz@transfore.nl
Phone number: (0546) 68 43 68
Tuesday through Friday

Data Protection Officer of the institution:

For more information about the processing of personal data, please contact the Data Protection Officer of the Dimence Group:

Dimence Group
Data Protection Officer
PO Box 5003
7400 GC Deventer
Email: privacy@dimencegroep.nl

For more information about your rights: https://www.dimencegroep.nl/kwaliteit-veiligheid or via: Authority for the Protection of Personal Data: https://www.autoriteitpersoonsgegevens.nl/

Appendix B: Consent form for participation in research Minddistrict

The effectiveness puzzle of eHealth: what is the added value of online interventions for the treatment of aggression in ambulatory patients in forensic care?

I have read the information letter for participation in the study. I could ask additional questions. My questions were answered enough. I had enough time to decide whether to participate.

I know that participating is completely voluntary. I know that at any time I can decide not to participate after all. I don't have to give a reason for that.

I know that some people can see my data. These people are mentioned in the information letter.

I give permission for my data to be used for the purposes stated in the information letter.

I give permission for my research data to be kept for 15 years after the end of this study.

I do/don't* want to receive a summary of the results when the study is completed. If so: please provide your email or address information here: _____

I do/do not* give permission to be contacted to participate in a possible interview (focus group).

I wish to participate in this research.

Name of participant:
Signature: Date : __/__ /____

_____

I hereby declare that I have fully informed this participant about the said research. If any information becomes known during the study that could affect the participant's consent, I will inform him/her in a timely manner.

Name of investigator (or his/her representative):
Signature: Date: __/__ /____

_____

Additional information was given by (if applicable):
Name:
Position:
Signature: Date: __/__ /____