Information letter for *Dialectical Behavior Therapy (DBT) for Patients with Autism, Emotion Regulation Problems, and Self-Injurious Behavior: A Multiple Baseline Single-Case Design*

August 20th, 2026

Information on Participating in a Research Study

Title: Dialectical Behavior Therapy (DBT) for Patients with Autism, Emotion Regulation Problems, and Self-Injurious Behavior: A Multiple Baseline Single-Case Design

Introduction

Dear Sir or Madam,

We are asking you to participate in a scientific study. Participation is voluntary. However, your (written) consent is required to participate. You are receiving this letter because you will soon start Dialectical Behavior Therapy (DBT) for patients with autism spectrum disorder (ASD).

Before you decide whether to participate in this study, this letter explains what the study entails. Please take your time to read through the information and ask the researcher for clarification if you have any questions. The researcher's contact information is listed at the end of this information letter. You may also discuss this with your partner, family, or friends.

This study is being conducted by the Scientific Research Department of GGZ Friesland. The Central Ethics Review Board of the UMCG has reviewed the study to ensure it complies with current Dutch legislation and additional UMCG regulations.

1. Background, Purpose, and Design of the Study

We are investigating the effects of DGT on emotion regulation problems in patients with autism spectrum disorder (ASD). Little is currently known about the effects of DGT in patients with ASD who have emotion regulation problems. The purpose of the study is to provide greater clarity, which may lead to improved treatments for this patient group. Using daily measurements, we aim to gain a better understanding of the effect of DGT on emotion regulation problems and how this effect develops over time. We aim to recruit six participants for this study. The ultimate goal is to publish our findings in a scientific journal.

2. What Participation Involves and What We Expect from You

Participating in the study means that the data from the diary form, which you fill out daily as part of your treatment, may be used for the study. This diary form is part of standard care, so you would fill it out even if you were not participating in the study. These diaries are essential for both your treatment and our scientific research. The data you provide helps us better understand the treatment and improve it for future patients. To ensure reliable research results, we need sufficient data. That is why we ask you to complete the diaries as thoroughly as possible. As a guideline, we aim for you to complete at least 5 out of 7 diaries per week (approximately 70% of the entries).

We also ask that you complete questionnaires on two separate occasions. These questionnaires cover social behavior, problems with emotion regulation, and general psychopathology and functioning. Completing the questionnaires takes approximately 23–33 minutes.

You have seven days to consider whether you would like to participate. We would like to hear from you within this time frame regarding your decision to participate. You can do so by signing the attached consent form and submitting it to your treating professional during your next visit.

3. Potential Benefits and Risks

It is important that you carefully weigh the potential benefits and risks before deciding to participate. You will not personally benefit directly from participating in this study. However, your participation can contribute to a better understanding of the effects and mechanisms of this treatment. This may lead to improved treatment for patients with ASD and emotion regulation difficulties in the future.

Potential disadvantages include:

- Being asked twice to complete an (additional) set of three questionnaires
- Being asked to fill out the diary card according to the therapist's instructions, just as you are asked to do as part of your treatment.

4. If you do not wish to participate or wish to withdraw from the study

You decide for yourself whether to participate in the study. Participation is voluntary. Your care will not change if you decide not to participate. If you do participate, you can always change your mind and withdraw, even during the study. You do not have to explain why you are withdrawing. However, you must notify your treating professional or the researcher immediately so that you are not contacted unnecessarily. You can do this verbally or by email (in writing) to your treating professional or the researcher. The data collected up to that point will be used for the study. you withdraw from the study but continue with your treatment, this will not affect your treatment.

5. Collection, Use, and Storage of Your Data

Your data will be collected, used, and stored for this study. Each participant will be assigned a code that will be used in the study data. Your name and other personal information that could directly identify you will be stored separately.

The following data will be collected for the study: age, gender, diagnostic information, data from the diary cards, and the questionnaires.

Confidentiality of Your Data

To protect your privacy, your data will be assigned a code. Your name and other information that could directly identify you will be omitted. The researchers and the data manager know which code corresponds to you. Data can only be traced back to you with the code key. The code key remains in the possession of the data manager. In reports and publications about the study, the data cannot be traced back to you.

Access to Your Data for Monitoring

Certain individuals at the study site may have access to all of your data, including unencoded data. This is necessary to verify that the study was conducted properly and reliably. Individuals who are granted access to your data for verification purposes include, for example, authorized monitors, auditors, and regulatory agencies such as the Health and Youth Care Inspectorate. They will keep your data confidential. We ask that you give your consent for this access.

Data Retention Period

Under applicable laws and regulations, the researcher is required to retain the data collected for the study for 15 years. After that, the data will be destroyed.

More information about your privacy rights can be found in GGZ Friesland's privacy statement. You can find it at: https://www.ggzfriesland.nl/over-ons/organisatie/privacy-en-informatiebeveiliging.

By signing the consent form, you are giving your consent to the collection, storage, and use of your medical and personal data as described in this information letter.

Other Uses of Data

We are requesting your consent to retain your data for potential future research at a later date. This will always involve research in the same field, which is either supplementary to or a follow-up of this study.

Follow-up Study

We also ask for your consent to contact you regarding a qualitative follow-up study. This study will examine the experiences of participants in the DGT treatment. On the consent form, you can indicate whether you agree to be contacted for the qualitative follow-up study. You can always withdraw this consent later if you change your mind.

If you do not wish to give your consent for this, you may still participate in this study.

6. Compensation for Participation

For faithfully completing the diaries, which are of great importance to the study, we are offering a compensation of €70. Participants who complete at least 70% of the diaries within the 3.5 hours that the diaries are open will receive compensation. This compensation is a token of appreciation for your time and effort. The compensation will be paid within two weeks after you stop participating. If you stop the treatment early, you may receive partial compensation. If you have completed at least 70% of the diaries by that point, you will receive compensation proportional to the number of weeks you participated.

Your contribution is invaluable to the success of this study. By participating, you are helping others who may benefit from improved treatments in the future. Do you have questions about filling out the diaries or the study? Please feel free to contact our team.

You will not receive reimbursement for travel and/or parking expenses, as participation in this study does not involve any additional appointments or travel.

7. Do you have any questions?

If you have any questions, please contact Sander de Vos, senior researcher at GGZ Friesland.

If you have any complaints about the study, you can discuss them with the researcher or your treating physician. If you would prefer to speak with someone not involved in the study, you may contact the complaints officer at GGZ Friesland.

If you have any questions or complaints regarding the processing of your personal data, we recommend that you contact the Data Protection Officer at GGZ Friesland: https://www.ggzfriesland.nl/over-ons/organisatie/privacy-en-informatiebeveiliging, phone number: +31 58 284 8802.

Best regards,

Sander de Vos, on behalf of the entire research team.

Research Team & Contact Information

Dr. Ernst Horwitz	Psychiatrist, A-level trainer
Milou Wiersum	Clinical psychologist, psychotherapist, treatment manager
Dr. Harriëtte Riese	Associate Professor

Dr. Jannis Kraiss Assistant Professor
Dr. Sander de Vos Senior Researcher
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Attachment: Participant Consent Form

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- I have read the information letter, *version 1.4, dated 20-08-2026*. I also had the opportunity to ask questions. My questions were answered satisfactorily. I had enough time to decide whether to participate.
- I understand that participation is voluntary. I also understand that I can decide at any time not to participate or to withdraw from the study. I do not need to provide a reason for doing so.
- I give my consent for the collection, use, and storage of my data in the manner and for the purposes described in the information letter.
- I understand that, for the purpose of monitoring the study, certain individuals may have access to all of my data. These individuals are listed in this information letter. I give my consent for these individuals to review my data.
- I understand that my data will be retained by GGZ Friesland for another 15 years.

Optional: *(You are not required to give consent for this in order to participate in the current study)*

- I give my consent to have my data stored after this study and used for other research or follow-up studies related to this study, as stated in the information letter:

O Yes

O No

- I give my consent to be contacted for a qualitative follow-up study, as described in the information letter:

O Yes

O No

- **I would like to participate in this study**

Participant's name:

Signature: Date:

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Researcher:

I declare that I have fully informed this participant about the aforementioned study.

If any information comes to light during the study that could influence the participant's consent, I will inform him or her of this in a timely manner.

Researcher's name (or representative's name):

Signature: Date:

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