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Information for participation in research

WARN-D II: A study investigating stress in the daily lives of young adults

Dear participant,

Thank you for your interest in joining WARN-D II, where we invite selected participants from the original WARN-D study to learn more about stress and mental health in young adults. WARN-D II is similar to the original WARN-D study, but it will only take 4 months from start to finish.

To be invited to our study, you need to be a WARN-D participant from Group 1 or Group 2. You also need to have a European (e.g. Dutch) bank account so we can compensate you for participation, and a smartphone that runs on Android or iOS (iPhone). Unlike the original WARN-D study, you can opt out of wearing a watch if you have a good reason (such as allergies or living far away). In order to receive a smartwatch, you need to reside in a country in the European Union, excluding all overseas territories such as the Dutch Antilles. If you live outside of the European Union, you can still participate in the study, but for logistical reasons you will not receive a smartwatch. We compensate you for your time (up to 48.75€ in total).

Please read **(1) the information sheet** and **(2) the informed consent form** below carefully and provide your digital consent if you'd like to be invited to our study.

If any questions remain after reading the information sheet and informed consent form below, please contact us at WARN-D@fsw.leidenuniv.nl.

Dr. Eiko Fried, in the name of the WARN-D research team

Associate Professor

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(1) INFORMATION SHEET

1. The WARN-D II study: Purpose and procedure

Young adulthood can be a stressful time, and some people experience mental health problems such as depression. The purpose of the WARN-D II study is to gain insight into how stressors and daily experiences contribute to mental health problems on the long term. The study has been approved by the ethics committee of the European Research Council, and by the Psychology Research Ethics Committee at Leiden University.

WARN-D and WARN-D II together will help us build the early warning system *WARN-D*, with the goal to predict mental health problems such as depression in students or young adults before they occur—similar to storm alerts. Understanding which individual participants are at risk of developing mental health problems will be a necessary first step towards personalized prevention programs. Unlike storms from which we can only run or seek shelter, there is a real chance we can prevent mental health problems altogether – if we understand the early signs.

2. What participation involves

This study can be done either in Dutch or in English. It is carried out in 3 stages and is conducted remotely, so you never have to meet the researchers in person. Although the structure of WARN-D II is similar to that of WARN-D, there are a few important differences between the studies, so **please read this section carefully**.

- **Stage 1:** For participants from Group 1 of WARN-D, the WARN-D II study starts with an online survey which takes around 30 minutes. This survey is similar to the surveys you know from Stage 3 of WARN-D. Participants from Group 2 of WARN-D will not receive this extra survey in Stage 1 of WARN-D II, they will complete the final survey of Stage 3 of WARN-D instead. All participants will also receive instructions for further participation at this point, e.g. how to install the two required smartphone apps.
- **Stage 2: If you live in the European Union**, we will send you a smartwatch (a black Garmin VivoSmart 4 – the same watch you used during the first WARN-D study) that you will wear for three months, if possible at all times except for when you need to charge it. If there are good reasons for not wearing the watch (not living in the EU, potential allergies, etc.), this is ok in WARN-D II, you can still participate without wearing a watch. The smartwatch collects activity data, such as your daily step count or sleep duration, via the app that you install on your smartphone. We will also use the *Avicenna* app (previously called *Ethica*, but is essentially the same app as the one you used during WARN-D) that you install on your smartphone to send you very similar surveys you're already used to (very brief surveys four times per day). They only take a few minutes and focus on your current mood, activities, and stress levels.

- **Stage 3:** After Stage 2 is over, you will return the smartwatch to us via mail (shipping costs are covered by us) and you can de-install the smartphone apps from your phone. Then we will send you one final 15-minute survey regarding your mental health.

We pay you for every survey you complete. Given the number of surveys we send you throughout the study, it is normal and okay to occasionally miss a survey.

3. Who can participate?

If you received an email from us, you are invited to participate in WARN-D II. This means you were part of Group 1 or Group 2 of the WARN-D study. You also need to have a European (e.g. Dutch) bank account so we can compensate you for participation, and a smartphone that runs on Android (version 7 or higher) or iOS (iPhone; version 13 or higher).

The study may not be suitable for some people because they may experience distress from participating. To ensure that this study is a good fit for you, we will ask you a few short questions after the information materials and informed consent before we can invite you to the study.

4. Advantages and disadvantages from participating

You can gain several benefits from participating in our study.

- If you live in the European Union, we will send you a *Garmin VivoSmart4* smartwatch that you can use for free for three months. Using the *GarminConnect* app, you will have access to all features of the smartwatch, and can use it to track your sleep, activity, receive notifications from your smartphone, etc.
- At the end of Stage 2, you will receive a free, detailed, individualized report of all the daily surveys you filled out during Stage 2. This report is a personalized summary of how your mood and experiences have changed during the three months of Stage 2, and it is created by researchers who are experts on mood dynamics and mental health. It is an upgraded version of the report you received during the WARN-D study, and now features an interactive interface where you can dynamically explore your data. The more questions you have answered, the more informative the report will be.
- For every survey you complete, you will be financially compensated. The maximum total amount is 48.75€.

A possible disadvantage of participation is that the study is quite time-consuming. Further, while some people enjoy tracking their own mood, others may find it uncomfortable to answer certain questions, for example about their stress or mental health problems such as depression. We do not expect any risks to your well-being from participating in our study. The smartwatch band you will be wearing is made out of silicone and skin reactions are very rare when used properly.

This is a purely observational study, not an intervention study. The content of your survey responses is *not* directly monitored or evaluated by the research team. While the ultimate goal is to build a warning system, this will not be done as part of this particular study in which you participate. You will not receive any warnings, diagnoses, or counseling from the research team. However, you will receive an information package with information on how to best find help in case you experience mental health problems.

5. What if you want to stop participating in the study?

Participation is completely voluntary. You can stop participation at any time, without having to provide a reason. If you stop, you will still get compensated for your participation up until that point. The data collected before will still be used for our research unless you ask us to delete it.

6. Compensation

You will be compensated up to 48.75€ for participating in this study; you can reach this maximum payment by completing all surveys in Stages 2, and 3. Compensation is proportional to the time you invest in the study; that means that you are paid more for a longer survey than a shorter survey, and you only get compensated for surveys you complete fully, and in time.

Stage	Time after study start	Activity	Financial compensation	Additional compensation
1	Month 0	30-minute survey	Compensated as part of WARN-D	
2	Month 1-3	4 surveys a day (2-5 minutes each), for 3 months	Up to 45€, depending on completed surveys	Free to use smartwatch (optional; only for participants living in the European Union); personalized report of daily surveys
3	Month 4	15-minute survey	3.75€	

7. Confidentiality, usage, and storage of your data

During your participation, we will collect, store, and use two types of data: **personal data** and **research data**. These types of data are used and stored in different ways.

7.1 Personal data

Personal data are data that can be directly linked to your identity, such as your name, address, phone number, and bank account.. We collect and use these data for logistic reasons. For example, we need to store your name and address in order to send you the smartwatch; your bank account in order to reimburse you; and your contact details in order to send you surveys and contact you in case of technical issues.

Your personal data will be stored securely. Some information such as your name, address, and financial information will be shared with the Leiden University financial department for processing your payment. The University is legally obligated to report participant payments to the Dutch Tax and Customs Administration; whether or not you have to pay taxes on these payments will depend on your personal situation. Your personal data will be deleted permanently after 10 years.

7.2 Research data

Research data are data that we use to answer scientific research questions, for example, questions about your well-being and daily stress. Research data are not directly linked to your identity.

Research data collected in WARN-D II will be linked to your research data collected during WARN-D to help us answer scientific questions about how mental health changes over time.

We are aware that mental health data are sensitive research data and we will take the necessary technical and organizational measures to ensure that they cannot be traced back to you. You will keep your pseudonym from the WARN-D study, which will be attached to the research data to minimize recognizability and traceability. From then on, we will only use the coded, pseudonymized data (i.e. without your personal data) for research. This de-identified research data will be stored indefinitely and shared publicly, so that other researchers and society can maximally benefit from your efforts as a research participant. This follows guidelines of the European Research Council and Leiden University, which have the aim to make research data Findable, Accessible, Interoperable, and Reusable (FAIR) in order to advance scientific progress.

7.3 Third parties involved

There are third parties involved in the research process. They will have access to parts of your data, and have all signed strict data processing agreements or independent controller-controller agreements with Leiden University.

- In Stages 1 and 3, *Qualtrics* will obtain your personal data for us, and research data from surveys

- In Stage 2, *Garmin* will collect your smartwatch research data for us, using the *GarminConnect* app on your smartphone; *Fitrockr* will obtain the Garmin research data for us; and the *Avicenna* app (previously called *Ethica*) on your smartphone will collect daily survey research data for us

7.4 General information about data use and storage

We only use methods approved by the IT Security of Leiden University and the European Research Council, and apply strict organizational measures regarding access rights, encryption, and security. All data are stored and processed in accordance with all rules and guidelines of the European General Data Protection Regulation (GDPR) in a well-secured manner. While privacy risks such as a data breach are minimal, they can never be fully ruled out. Please take this into consideration when deciding whether to participate in the study. When you sign the declaration of consent, you consent to the collection, storage, and use of both your personal and research data in the above-outlined ways.

This research is conducted by Leiden University, which is responsible for the data processing. Questions, comments, or complaints concerning the way your data are handled can be addressed to the responsible researchers (WARN-D@fsw.leidenuniv.nl), the Data Protection Officer of Leiden University (privacy@bb.leidenuniv.nl), or the Dutch Data Protection Authority (<https://autoriteitpersoonsgegevens.nl>).

For any questions or issues during the study, you can email us or send us messages via *WhatsApp* to 06-2831-9154 (Dutch number, i.e. +31-6-2831-9154). Please note that if you use *WhatsApp*, the terms and conditions of *WhatsApp* regarding data privacy apply.

8. Who is funding the research

This study is part of a five-year project funded by the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation program (Grant agreement No. 949059). The research is carried out by Dr. Eiko Fried and his research team at Leiden University.

9. Any questions?

Please don't hesitate to contact the research team at WARN-D@fsw.leidenuniv.nl.



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2. STATEMENT OF INFORMED CONSENT

1. Did you understand the information correctly?

To ensure that you have understood all information correctly, please tick the correct statements below (only one is correct per answer).

Question 1: In our study...

- you will not be financially compensated.
- you will be financially compensated according to the number of surveys you complete, up to 48.75€ in total.
- every participant receives a financial compensation of 48.75€.

Question 2: Our study is...

- a clinical study in which participants who show signs of depression will be warned by the researchers and offered treatment.
- a purely observational study; no diagnoses or warnings will be given to participants who show signs of mental health problems, and no treatment will be offered by the researchers.

2. Do you meet the inclusion criteria

To participate, you need to meet all inclusion criteria. Please confirm whether the following statements apply to you.

- I am a WARN-D participant from Group 1 (WARN-D starting date November 2021) or Group 2 (WARN-D starting date May 2022)
- I own a smartphone with either Android operating system (version 7 or higher) or iOS operating system (version 13 or higher)
- I have a European (e.g. Dutch) bank account (IBAN)

Some people could not wear the smartwatch as intended during WARN-D, for example, because of allergic reactions or job regulations. If you can only participate in WARN-D II without wearing a smartwatch, please indicate this below:

- I can wear a smartwatch during WARN-D II
- I cannot wear a smartwatch during WARN-D II for the following reason: _____

3. Informed consent

In order to be invited to and to participate in our study, you need to give consent to all statements below by ticking the respective boxes.

- I would like to participate in this study. I have read all the information on the previous pages. I was able to direct questions via email to the researchers. If I had questions, they have been answered to my satisfaction. I had enough time to decide whether to participate.
- I know participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this. My decision to take part or not take part, or to later withdraw from the study, will not affect my grades, relationship with my teachers, or standing at my school. If I decide to withdraw, I will still receive financial compensation for the amount of time I invested into the study up to that point.
- I consent to my data being used and stored in the way and for the purpose stated in the information sheet. This includes 1) my data being collected by third parties mentioned above; 2) my personal data being stored for 10 years after this study, after which time they will be deleted permanently; and 3) my de-identified (i.e. anonymous) research data being linked to my research data collected in WARN-D, being stored indefinitely, and shared publicly so that other researchers and society can maximally benefit from my efforts as a participant.
- I consent to being contacted by the WARN-D research team, e.g. when technical or procedural issues occur, or for an invitation to a follow-up study.

4. Neighborhood data

The Netherlands collects information about the neighborhood people live in, stored in so-called registries. These registries include information on traffic noise, air pollution, safety, and the value of houses. We want to look up information about your neighborhood based on the address you provide us with. Do you give us permission to do so? We believe that this information can help us understand stress and mental health better, but you can participate in our study no matter if you choose yes or no.

- Yes, I give permission
- No, I don't like that

Date: _____

Name: _____

Email address: _____