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Information for participation in research

WARN-D: A prospective study investigating stress in the daily lives of students

Dear participant,

Thank you for your interest in joining our two-year study on stress and mental health in students, WARN-D.

To be invited to our study, you need to be at least 18 years old; fluent in reading Dutch or English; study at a Dutch educational institution, pursuing an MBO, HBO, or WO/university degree; and currently live in the Netherlands, Germany, or Belgium. 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).

Please read the information sheet below carefully and provide your digital consent if you'd like to be invited to our study. We compensate you for your time (up to 90€ in total) and through two additional lotteries of 500€ each.

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

Leiden University, Department of Clinical Psychology

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WARN-D@fsw.leidenuniv.nl

INFORMATION SHEET

1. The WARN-D study: Purpose and procedure

Studying can be a stressful time, and some students experience mental health problems such as depression. We want to understand better what stressors students experience, and how they deal with them. To do so, we zoom into the daily lives of students, closely monitoring their daily activities and experiences for a period of three months, combining brief daily questionnaires via smartphones, and activity tracking via smartwatches. Following these three months of daily measurements, we will follow students' experiences through online questionnaires every three months, for a total study period of two years. The study has been approved by the ethics committee of the European Research Council, and by the Psychology Research Ethics Committee at Leiden University.

The collected data will help us build the early warning system *WARN-D*, with the goal to predict mental health problems such as depression in students before they occur—similar to storm alerts. Understanding which individual students 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 is a two-year online study, and can be done either in Dutch or in English. The study is carried out in 3 stages; participation in Stage 1 is necessary for participation in Stages 2 and 3. The survey is conducted remotely, you never have to meet the researchers in person. Participation lasts two years in total.

- **Stage 1:** The study starts with an online questionnaire which takes around 90 minutes. This includes questions regarding your socio-demographic background, stress, and (mental) health. You will also receive instructions for further participation, e.g. how to install the two required smartphone apps.
- **Stage 2:** After completing Stage 1, we will send you a smartwatch (a black Garmin VivoSmart 4) that you will wear for three months, if possible at all times except for when you need to charge it. The smartwatch collects activity data, such as your daily stepcount or sleep duration, via the *GarminConnect* app that you install on your smartphone. In Stage 2, we will also use the *Ethica* app that you install on your smartphone to send you very brief surveys four times per day. These surveys 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. From then on, we will send you short online surveys every three months via email, to see how you have been doing. These surveys take about 15 minutes each. At the end

of the first and second year of the study, surveys will be a little longer, around 30 minutes instead of 15. To reward you for your continued efforts, you can take part in two yearly lotteries of 500€ by answering those two 30-minute surveys.

Given the number of surveys we send you throughout the study, it is normal and okay to occasionally miss a survey. Missing a survey means that you will not get reimbursed for that survey. There are no other consequences, and you can continue participating in other surveys for the remaining study period (except for Stage 1 survey, which needs to be filled out in full).

3. Who can participate?

To be invited to this study, you need to be at least 18 years old; fluent in reading Dutch or English; study at a Dutch educational institution, pursuing an MBO, HBO, or WO/university degree; and currently live in the Netherlands, Germany, or Belgium. You 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.

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.

- We send you a Garmin VivoSmart4 smartwatch that you can use for free for three months. Using the *GarminConnect* app, you have access to all features of the smartwatch, and can use it to track your sleep, activity, receive notifications from your smartphone, etc.
- After three months, at the end of Stage 2, you will receive a free, detailed, individualized report of all the daily questionnaires 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. Some insights you may get from this report could be, for example, how your mood is affected by your sleep or exercising. To ensure sufficient quality of the report, you need to have answered at least 50% of the daily questions.
- For every questionnaire you complete, you will be financially compensated. The total overall amount is 90€. In addition, there will be two lotteries among participants who complete the surveys at the end of the first and second year of the study. Here, you can win an extra 500€ each time.

A possible disadvantage of participation is that the study is quite time-consuming. Further, while some students 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, all participants 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 are free to stop participation at any time, without having to provide a reason (although you are free to do so of course). 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 90€ for participating in this study; you can reach this maximum payment by completing all surveys in Stages 1, 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.

We expect that over the course of two years, surveys take ~16 hours in total, and you receive on average 5,30€ per hour. Below you find an overview of what compensation you can expect at which stage of the study.

Stage	Time after study start	Activity	Financial compensation	Additional compensation
1	Month 0	Baseline survey and instructions (90 minutes)	7,50€	
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; personalized report of daily surveys

3	Months 4-24	6 short surveys (~15 minutes each, 1 every 3 months) 2 longer surveys (~30 minutes each, 1 every 12 months)	Up to 37,50€, depending on completed surveys; 3,75€ per short survey; 7,50€ & lottery ticket per long survey	2 lotteries of 500€ each
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Note that all minutes in the table above are approximations. Some participants may fill out surveys a little faster, others a little slower. Payments will be processed after Stage 2, year 1, and year 2 of the study period.

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, bank account, and citizen service number (BSN; only in case you live in the Netherlands). 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 BSN number (if you have one), and 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, BSN number (if you have one), 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.

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. In the beginning, every participant gets a code (pseudonym) 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 *EthicaData* app 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 University of Leiden's IT Security 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.

Eiko Fried

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

Associate Professor

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