Validation and norming of Mindmore's digital cognitive screening.

Information to research participants

We would like to ask you if you would like to participate in a research project. This document provides information about the project and what it means to participate.

What kind of project is it and why do you want me to participate?

Tests of memory and cognition (thinking) are used today to detect brain damage and certain diseases. Mindmore AB (org.nr. 559120-7401) develops a service of digital neurocognitive tests. Mindmore's tests are similar to those traditionally used in health care with the one difference that it is the digital solution that administers and leads the tests instead of a trained psychologist, doctor or test leader. In this way, we hope that it will be easier and cheaper to measure cognition and memory. If testing becomes easier and cheaper, it would be possible to test patients earlier and/or more often.

Since the tests are now carried out digitally instead of with pen, paper and test leader, we need to conduct research studies to evaluate the tests accuracy and to build up a normative data base of healthy adult individuals with which to compare patient test data.

If you have been asked to participate in this study, you are over 15 years old, have English as your mother tongue and have no known cognitive impairment.

This research project is conducted by Mindmore AB which means this is the organisation responsible for the study.

How does the study work?

Study participation includes two steps, each performed on your own device and at a time of your choice:

1. you complete an online questionnaire (20 min)
2. you take the digital cognitive test (45-60 min).

The questionnaire starts with asking for your consent to participate in the study. Following are questions about you, your health (e.g., use of medication and diagnoses related to cognition), and the device you'll use to take the test. This information is used to assess if you pass the study in- and exclusion criteria and which tests to invite you to. If we have questions to you concerning your answers in the questionnaire we will try to reach you per telephone.

When you are included in the study you will receive a link to the cognitive test. You have 7 days to complete the tests. You are asked to find a quiet space and you need a laptop with functioning audio and microphone (a headset may be used). The test includes different parts together measuring a range of cognitive functions, such as memory, attention and focus.

Some tests require you to speak to your device and to score your results sound is recorded during these tests only.

The results of the digital tests are stored digitally on a server. The results are archived and stored pseudonymously according to research ethical principles.

Possible consequences and risks of participating in the study

This study method does not affect your health and your participation does not pose any risks to you. The tests also do not contain any images, messages or other content that may be perceived as offensive. The only thing your participation "costs" is your time spent conducting the tests.

After your participation in the study, you will receive your result. You will then learn how your memory and thinking is reflected itself in the test. In the event that you get an anomalous result, e.g. when more than half of the cognitive abilities are 'below average', a clinical psychologist will offer to go through the result with you. There is also always the possibility to approach the responsible researcher with questions about the study.

What happens to my data?

The project will collect and record information about you.

Your results will include so-called health data about you, as the tests provide information about your thinking and your memory. This data is stored digitally on secure servers that comply with the requirements set out in the GDPR (EU General Data Protection Regulation).

This means, among other things, that access to data is strictly limited to what is stated here, in the consent that you will be asked to sign, as well as that there is confidentiality for us at Mindmore who have access to the data.

The collected data will be pseudonymised, replacing all identifying features in our database with an alphanumeric code such that the data cannot be traced back to you from the database. Separately, another document will contain a code-key which enables us to connect you to the data stored in the database. Both test data and code-key are encrypted and stored safely on servers in the EU. They are stored in different places, each in a digital equivalent of a locked cabinet.

The only data collected is the data you provide to us. Personal data relating to health and medication is collected to determine whether you meet the inclusion criteria for the study. Personal data such as email address is collected to send you your result. Your test results will be entered into data analysis. Statistics will be performed at group level, including all study participants, normative models based on this analysis are intended for implementation in

the Mindmore result portal and scientific publication.

According to the Code of Research Ethics, we need to store the personal data five (5) years after the scientific article has been published. During this time, the personal data is pseudo-anonymized. Personal data is de-identified after five years, which means the code-key is destroyed and with that the data can no longer be linked to a specific person.

Data will not be shared with any other company, university or business within or outside Sweden.

Your answers and your results will be processed so that unauthorized persons cannot access them.

The person responsible for your personal data is Mindmore AB. According to the EU General Data Protection Regulation, you have the right to access the information about you handled in the study free of charge, and if necessary, have any errors corrected. You can also request that data about you is deleted and that the processing of your personal data is restricted. If you want to access the information, you should contact the person responsible for the study (see below). The Data Protection Officer can be reached at info@mindmore.com. If you are dissatisfied with how your personal data is processed, you have the right to lodge a complaint with the Swedish Data Protection Authority, which is the supervisory authority.

What happens to my results?

The results may only be used in the way that you have given consent to. If there should be research that is not yet planned, the Ethical Review Board will decide whether you should be consulted again.

How to get information about the results of the study?

The results of the study will be published in a scientific journal and a summary will be available via Mindmore's website. All results are published at group level and no information can therefore be linked to you or any other individual.

Insurance and compensation

In addition to feedback, no monetary compensation is paid to research participants. You receive no additional insurance during study participation.

Participation is voluntary

Your participation is voluntary, and you may choose to cancel participation at any time. If you choose not to participate or wish to discontinue your participation, you do not need to state why, and it will not affect your future care or treatment.

If you wish to discontinue your participation, please contact the person responsible for the study (see below).

Responsible for the study

Responsible for the study is Wobbie van den Hurk, MSc (072 852 51 55; wobbie@mindmore.com), Ludwig Franke Föyen (ludwig.frankefoyen@mindmore.com) and Anders Gustavsson PhD (anders.gustavsson@quantifyresearch.com).

The authorized representative of the research principal is Operations Manager Mindmore AB Sara Wallén (sara@mindmore.com).

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Consent to participate in the study

I have received oral and written information about the study via email, the ‘Information to research participants’, and have had the opportunity to ask questions. I may keep the written information.

☐ I consent to participate in the study Validation and norming of Mindmore's digital cognitive screening (Swedish: Validering och normering av Mindmores digitala kognitiva screening).

☐ I consent to the processing of data about me in the manner described in the information to research participants.

☐ I consent to my results being saved in the manner described in the information to research participants.