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The effects of a stress-monitoring smartphone application for autistic adults

Submission date
18/04/2023

Recruitment status
No longer recruiting

Registration date
19/04/2023

Overall study status
Completed

Last Edited
27/06/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Adults with autism consistently experience more daily stress compared to non-autistic adults. Regular stressful experiences can negatively affect one's mental and physical health, which in turn may increase one's susceptibility to experience even more stress. There is therefore a need for simple, widely accessible interventions that reduce the daily stress load of autistic adults by supporting them in recognizing, monitoring and managing their daily stress. This study aims to investigate the effectiveness of SAM-NAR, a stress-monitoring smartphone application for autistic adults.

Who can participate?
Adults (aged 16 years and older) with autism who are registered in the Netherlands Autism Register and who have a smartphone

What does the study involve?
Participants will be randomly distributed into two groups. One group will use the SAM-NAR smartphone application for 4 weeks, while the other group waits for 4 weeks before they also get access to the application. Both groups fill in online questionnaires at two timepoints: at the beginning of the study (before using the app) and 4 weeks after the start of the study (after one group used the app for 4 weeks). These assessments include questions on perceived stress, coping skills, and mental wellbeing.

What are the possible risks and benefits of participating?
Participants may benefit personally because the SAM-NAR app can give them more insight into their stress level and which factors contribute to this. Participants contribute to a science-led knowledge base on daily life factors which contribute to stress and well-being of adults with autism.
Participation requires time and effort. Using the SAM-NAR app takes between 4 and 12 minutes per day for a period of 4 weeks. Participants could experience more stress by using the app. If they find that this is the case, they can always choose to stop using the app. Participants may become more aware of their own stress or the stimuli that lead to more stress. This awareness can be perceived as annoying.

Where is the study run from?
The study is run from the Netherlands Autism Register at the Vrije Universiteit Amsterdam (Netherlands). However, all assessments and application usage will take place online and are thus not location-bound.

When is the study starting and how long is it expected to run for?
January 2023 to May 2023

Who is funding the study?
Dutch Research Council (NWO) (Netherlands)

Who is the main contact?
Dr Anke Scheeren, a.m.scheeren@vu.nl

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of a smartphone application (SAM-NAR) compared to a waitlist-control in reducing stress in autistic adults: a randomized controlled trial

Acronym
SAM-NAR

Study objectives
Research question: What is the effectiveness of the SAM-NAR application on the stress and well-being of autistic adults?

Hypothesis: The intervention group that uses the SAM-NAR app for 4 weeks will show a stronger decrease in their stress level compared to the waitlist control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2023, the ethics committee of the Faculty of Behavior and Movement Sciences of the Vrije Universiteit Amsterdam (Van der Boechorststraat 7, 1081 BT Amsterdam, Netherlands; +31 (0)20 59 88732; vcwe.fgb@vu.nl), ref: VCWE2023024R1

Study design
Interventional parallel non-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Stress reduction in adults with autism spectrum disorder

Interventions
Participants receive an email with a link to the baseline assessment (pre-test): an online questionnaire regarding stress and wellbeing. At the end of this questionnaire, randomization occurs automatically by a built-in “Randomizer” tool from Qualtrics (Qualtrics, Provo, UT). Participants are allocated to either the intervention group or a waitlist-control group. Participants are informed via email about their group status right after the baseline assessment. Additionally, participants in the intervention group receive instructions on how to download and use the SAM-NAR app, a stress-monitoring smartphone app designed specifically for autistic adults (please see below). Waitlist-control participants are informed that they can make use of the smartphone application after 4 weeks. Four weeks after the pre-test, all participants receive an automatic email with a link to the post-test. After the post-test, waitlist-control participants receive instructions on how to download and use the SAM-NAR app. Due to the nature of the study, no blinding of the participants or researchers could be realized.

SAM-NAR application
The SAM-NAR application is a mobile health application designed for autistic adults to help them recognize, monitor and manage their stress in everyday life. The Stress Autism Mate (SAM) app, a precursor app which is very similar to the SAM-NAR app, was developed by a project group consisting of mental health researchers of the Netherlands organization for applied scientific

research (TNO), clinicians of Ggz Centraal, an organization for specialist mental health care in the Netherlands, and fifteen individuals with autism. The SAM-NAR is an extended version of the SAM-app, including additional questions developed by the Netherlands Autism Register (NAR).

Using the SAM-NAR app involves filling in short questionnaires on a regular and daily basis. Users receive a request from the app to complete a short questionnaire at 2, 3, or 4 fixed moments each day (depending on the preference of the participant), with a 4-hour interval. Participants can set the time for the first questionnaire. Each questionnaire takes approximately 2 to 3 minutes to complete. On a daily basis, usage of the application therefore takes 4 to 12 minutes. Preferences with regard to layout, number of assessments per day, and timing of the first questionnaire can be altered at any time by the participant.

During these brief daily assessments, the SAM-NAR app prompts the user with multiple-choice questions regarding their environment in the past 4 hours (e.g., being alone or with others), what activities they were doing in the past 4 hours, and how they felt during these activities. The app then asks questions about the presence of stressful feelings or thoughts in the past 4 hours, such as 'Did you feel irritable?' and 'Were you dreading activities on your schedule?'. Answers to these stress-related questions are summed to create a total score corresponding to various intensities of stress: no stress, little stress, stress, much stress. With the use of an algorithm, an automatic report of the level of perceived stress is generated and available to the user directly after filling in the questions. The stress level of the user is then verified by asking if this report matches the user's own perception of stress. Discrepancies between the user's stress levels as assessed by the application and as perceived by themselves are registered. Please see Hoeberichts et al. (2022) for more information on the SAM application.

Intervention Type
Behavioural

Primary outcome(s)
1. Level of perceived stress is measured via online questionnaires using the 10-item Perceived Stress Scale (PSS-10) at baseline (pretest: T0) and 4 weeks after baseline (post-test: T1)
2. Mental wellbeing will be assessed with the 14-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline (pretest: T0) and 4 weeks after baseline (post-test: T1)

Key secondary outcome(s))
Coping skills will be assessed with the 13-item Coping Self-Efficacy Scale (CSES) at baseline (pretest: T0) and 4 weeks after baseline (post-test: T1)

Completion date
03/05/2023

Eligibility

Key inclusion criteria
To be eligible for this study, participants ought to:
1. Be at least 16 years old
2. Have a formal diagnosis of Autism Spectrum Disorder
3. Be a self-reporting participant in the Netherlands Autism Register
4. Be in possession of a smartphone or tablet for using the SAM-NAR application

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
214

Key exclusion criteria
1. People who are not registered in the Netherlands Autism Register

Date of first enrolment
14/03/2023

Date of final enrolment
04/04/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije Universiteit Amsterdam
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
Vrije Universiteit Amsterdam

Funder(s)

Funder type
Research council

Funder Name
Nederlandse Organisatie voor Wetenschappelijk Onderzoek [AUT.17.006]

Alternative Name(s)
Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
The Netherlands Autism Register will store the data non-publicly.
The datasets generated during and/or analyses during the current study will be available upon request. Please note these data do not include individual user data collected with the help of the SAM-NAR app, but include survey data collected at pre- and post-test.
Researchers who want to collaborate with the Netherlands Autism Register can fill out the form at the NAR website (https://nar.vu.nl/samenwerken_met_het_nar/werken_met_nar_data/) and /or contact the NAR via info@nederlandsautismeregister.nl. The data request will be reviewed by the NAR team. Once the NAR team has reviewed the request (typically within 2 weeks) the researchers will be informed of the outcome. If the request is not approved, researchers may be requested to revise the proposal and resubmit.
Once the data request is approved, researchers will be asked to sign a data sharing agreement (DSA). Once the NAR team receives the signed data-sharing agreement, data management will prepare the dataset. A typical data request takes approximately 2 weeks to prepare. If the request is particularly complex or if the request comes at a very busy time, more time may be needed. If this is the case, researchers will be informed of this by NAR data management.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/06/2025	27/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes