Towards accurate screening and prevention (2-ASAP): PTSD risk screening study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON53786

Source
ToetsingOnline

Brief title
2-ASAP: PTSD Risk screening study

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress, Posttraumatic stress disorder (PTSD)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW;de Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie.

Intervention

Keyword: Machine learning, Prognostic risk screening, Prospective, PTSD

Outcome measures

Primary outcome

The main study parameter is the Area under the Receiver Operator Characteristic curve (AUC) of the derived machine learning algorithms, reflecting the accuracy in correctly classifying participants in the respective test sets into the adverse latent PTSD symptom trajectories. These adverse latent PTSD symptom trajectories are determined from the PTSD symptom severity measured across assessments (TraumaTIPS: CAPS total score, 2-ASAP: PCL5 total score). The machine learning algorithms are based on information collected from self-report questionnaires at the baseline assessments, relating to demographic characteristics, details on current and previous trauma exposure and related emotions, cognitions and social support and current and immediate past psychological and physical health symptoms.

Secondary outcome

The baseline assessment additional includes current best-practice screening instruments for PTSD (secondary outcomes). The follow-up assessments additionally includes self-report questionnaires on co-morbid psychological symptoms and functional and economic outcomes (secondary outcomes).

Study description

Background summary

Upon exposure to traumatic events involving (threatened) death, injury or violated physical integrity, a substantial minority of individuals subsequently develops the psychiatric disorder posttraumatic stress disorder (PTSD). There are increasing indications for sex differences in PTSD*s symptom course and underlying etiological mechanisms.
Only the first weeks post-trauma provide a unique window of opportunity for preventive interventions. Such preventive interventions can decrease PTSD prevalence and relatedly improve wellbeing, functioning, quality of life, and reduce health care use, productive loss and associated costs. Importantly, while there are several promising preventive interventions, it has now become clear that preventive interventions are only feasible and effective if delivered as indicated preventive intervention to individuals at high risk for PTSD. There are currently no prognostic screening instruments accurately classifying individuals* risk for an adverse PTSD symptom course that can be administered to a broad population of acutely trauma-exposed individuals within the first weeks thereafter.

Study objective

The primary objective of this study is to derive and externally validate a prognostic screening instrument to predict individual risk to follow an adverse PTSD symptom trajectory over the course of one year following trauma based on self-report information on previously identified PTSD risk and protective factors collected early post-trauma using sex-disaggregated machine learning algorithms. Secondary objectives are to investigate potential novel PTSD risk and protective factors and update the prognostic screening instrument; differences in co-morbid psychological symptoms; functional and economic outcomes between individuals classified as low versus high risk; and to compare the accuracy of the derived prognostic screening instrument with current best practice screening instruments for PTSD.

Study design

The study uses both existing and newly to be collected observational prospective cohort data. Both cohorts include a first baseline assessment within the first weeks post-trauma and include 4 follow-up assessments until one year posttrauma.

Study burden and risks

For the new cohort, all data is derived from online self-report questionnaires. There will be no direct benefits for the subjects to participate in the study. The assessment of the potential risk relating to the participant*s safety and wellbeing is somewhat higher than that of standard medical care/normal daily life, due to the potential disquieting nature of the questionnaires. The final

risk classification is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this cohort, a participant must meet all of the following criteria:
- Age 18 years or older;
- Experience of an traumatic event according to DSM-5 PTSD A criterion (i.e. involving actual or threatened death, violence or violation of physical integrity) maximally 60 days posttrauma at baseline.
- The traumatic events need to be directly experienced by the participant themselves, have an acute onset, external cause and the potential to lead to

serious physical injury (i.e. not a medical condition).

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation:

- Evidence of homicidality, suicidality, injuries due to intentional self-inflicted injury;
- Evidence of ongoing or repeated trauma exposure, such as ongoing domestic violence;
- Evidence of an inability to understand study procedures, risks or being otherwise unable to give informed consent;
- Evidence of being unable to follow protocol (due to any reason, including visual or cognitive or physical impairment precluding completion of protocol);
- Impairment in ability to use or no regular access to internet-connected smartphone, tablet or computer for completion of online assessments;
Insufficient understanding of Dutch language to follow protocol

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-07-2022
Enrollment:	863
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	21-04-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-07-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-03-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL80296.018.22