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Last Update: 06/15/2020 12:13

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	FORTE2018-00402
Brief Title:	Sustainable UNiversity Life (SUN) Study.
Official Title:	Sustainable UNiversity Life (SUN): Mental Illness and Pain Conditions Among Students - a Cohort Study to Identify Modifiable Risk and Prognostic Factors.
Secondary IDs:	

Study Status

Record Verification:	March 2020
Overall Status:	Enrolling by invitation
Study Start:	August 19, 2019 [Actual]
Primary Completion:	January 31, 2022 [Anticipated]
Study Completion:	January 31, 2032 [Anticipated]

Sponsor/Collaborators

Sponsor:	Sophiahemmet University
Responsible Party:	Sponsor
Collaborators:	Karolinska Institutet Forte

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 2019-03276 Board Name: The Swedish Ethical Review Board Authority Board Affiliation: Medicine Phone: +4610475 08 00 Email: registrator@etikprovning.se Address: The Swedish Ethical Review Board Authority Box 2110 750 02 Uppsala

	Sweden
Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary:

In 2017, Socialstyrelsen reported that mental ill-health in young adults had increased by almost 70% in the previous10 years. A 2014 report showed that 5% of men and 11% of women 18-24 years were diagnosed with depression or anxiety in Stockholm County. Furthermore, 41% of women 21-24 years have self reported psychological distress. Regarding pain, 28% of men and 36% of women 16-24 years have disabling neck pain. Little is known about the etiology and prognosis of poor mental health in university students.

The aim is to advance knowledge about the etiology of depression, anxiety, stress and pain in undergraduate university students. We will study a cohort of students at full-year programs at universities in the Stockholm area. Primary research questions are whether modifiable factors such as sleep quality, lifestyle, screen time and work environment are independent risk factors for incident episodes or unfavorable trajectories of depression, anxiety and pain in men and women? To be able to answer these research questions we designed a prospective cohort study targeting 5000 university students.

Detailed Description:

Study objectives:

The overall study aim is to advance the knowledge about the etiology and prognosis of common mental health problems (depression, anxiety and stress) and musculoskeletal pain experienced by undergraduate university students in Sweden.

Specific research questions:

Are modifiable factors as bad sleep quality, meal patterns, low physical activity/ sedentary lifestyle, pain conditions and bad study environment independent risk factors of incident episodes of troublesome depressive and anxiety symptomatology and musculoskeletal pain and of unfavorable trajectories of depressive, anxiety, stress and pain symptoms? Are modifiable factors as bad sleep quality, meal patterns, low physical activity/sedentary lifestyle, pain conditions and bad study environment independent prognostic factors for recovery from troublesome depressive and anxiety symptomatology and musculoskeletal pain? Do such potential risk factors and trajectories vary between men and women? What are the trajectories of sleep quality, meal patterns, physical activity/sedentary lifestyle, pain and substance use during one academic year (describe the fluctuations of risk factors)?

Study design:

Cohort study of undergraduate full time program students followed-up four times during an academic year.

Source populations:

The source populations for this project are undergraduate full-time program students at universities in the Stockholm area.

Data collection:

Data collection will be performed with questionnaires through a link sent to students e-mail address, provided by the participating universities. The students will be able to access the questionnaire for a four-week period at baseline and each follow-up.

Exposures:

Sleep quality, physical activity and sedentary behavior, substance use in the past three months (non-medical use), study environment, body image, perfectionism, gambling, compulsive exercise, social media use, cyberbullying, procrastination and loneliness.

Outcomes:

Outcomes will be measured with the Depression Anxiety Stress Scales-21 (DASS-21). The DASS-21 includes three subscales designed to measure depression, anxiety and stress symptoms in non-clinical populations. Musculoskeletal pain will be measured with the The Nordic Musculoskeletal pain Questionnaire that cover most potential musculoskeletal pain sights.

Potential confounders:

We will collect the following variables as potential confounders of the association between the exposures and the outcomes. These confounders were selected based on our review of the literature.

Sociodemographic variables: age, gender, citizenship, marital status, number of dependents, parents' marital status, parents' employment status, annual personal and household income, hours of work per week, living arrangement, and commute time.

Academic variables: Overall average in the past year (first year students will provide the average for the final year of high school), program of study, year of study.

General health and medically diagnosed comorbidities: We will ask participants to rate their general health and comorbidities diagnosed by a health care provider in the past year. We will selected comorbidities that are reported by > 5% of the sample in our pilot study. In the Canadian pilot study, these include: allergies, arthritis, asthma, attention disorder/learning disability, eating disorder, hypertension, intestinal or stomach ulcers, migraine headaches, mood disorder, scoliosis, and sexually transmitted infections.

Data analysis and statistics:

Definition of trajectories: Trajectories of the outcomes depression, anxiety, stress symptoms and pain will emerge by latent class growth mixture models (LCGMM) that allows for the identification of multiple underlying trajectories within a defined population. In LCGMM, each trajectory is defined by its own growth parameters (intercept, linear slope), which are assumed to be latent. We will use the Baysian Information Criteria (BIC), Bootstrap Likelihood Ratio Test (BLRT) and entropy (measure of uncertainty) to determine whether our 4-trajactory hypothesis offers the best fitting solution for the data. Also trajectories of sleep quality, food insecurity, physical activity/sedentary lifestyle, and substance use will be identified with this method.

Associations between exposures and trajectories: We will use multinomial logistic regression analyses to determine the associations between each of the exposures and trajectories of outcomes. We will report the associations as odds ratios (OR) and 95% confidence intervals (95% CI). We will first build bivariate models to measure the crude associations between the exposures and trajectories. To identify confounders, we will build models to test whether the inclusion of each potential confounder produced a ≥ 10% change in any of the associations.

Associations between exposures and incident cases of depression, anxiety, stress symptoms and pain: At baseline, we will identify a sub-cohort of students at risk of developing troublesome depressive and anxiety symptoms and pain respectively. We will use Kaplan-Meier estimates to describe the incidence

and discrete time survival analysis to measure the associations between the exposures and the outcome. In all models, the reference category will be the level of exposure hypothesized to be associated with the lowest risk of the outcome. ORs and 95% CIs will be used to describe the strength and direction of association. The same approach as described above will be used to identify prognostic factors (starting with a sub-cohort under "risk" of recovery) and for control for confounding.

Sample size: We estimated the number of parameters that could be included in our multinomial logistic regression models based on distributions of participants across the four hypothesized trajectories (no symptoms; improvement; worsening; and persistent) using two diverse distribution scenarios. In scenario 1, we hypothesized that 70% have no symptoms, 13% experience worsening, 10% improve and 7% have persistent symptoms. In scenario 2, we hypothesized equal distribution (25%) across trajectories. Based on these assumptions, we estimated that our models could accommodate between 32 parameters if we recruit 1000 students (scenario 1) to as many as 234 parameters if we recruit 5000 participants (scenario 2).

Covid-19 sub-study:

The recruitment and data collection for our cohort study took place before and during the Covid-19 pandemic.Therefore, we started a more fequent recording of levels of pain, axiety and depression from May 2020 with weekly text messages. The data Collection before and during the pandemic provide a chance to investigate the change in symptoms of depression, anxiety and stress and lifestyle behaviors in relation to the pandemic. Our specific research questions with regards to this Covid-19-related sub-study are: 1) Are there any changes regarding symptoms of mental health problems during the first month of the pandemic? 2) Will students display changes in healthy lifestyle behaviors such as sleep patterns and quality, meal pattern, exercise and substance use during the first month of the pandemic and 3) Different trajectories of symptoms of low mood, worry and pain during the course of the pandemic will be measured weekly with the aim of identifying factors related to unfavorable trajectories.

Conditions

Conditions: Mental Health Issue
Musculosceletal Pain, Disabling Pain

NOTE : "Musculosceletal Pain, Disabling pain" is not a recognized condition

Keywords: cohort study, Depression, Anxiety, Stress, Pain, Lifestyle, Students, Risk factors, Prognostic factors

NOTE : Keyword should have no more than 60 characters.

Study Design

Study Type: Observational

Observational Study Model: Cohort

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 5000 [Actual]

Number of Groups/Cohorts: 1

Groups and Interventions

Groups/Cohorts	Interventions
SUN-participants University students enrolled in a selected university in Stockholm, studying on a full-time educational program with at least one academic year left before graduation. There is no intervention. The exposures are repeated measures, 5 times (every three months), using web-based self-report questionnaires during one academic year. Also weekley SMS are used to measure depression, anxiety and pain intensity.	Web-based self-report questionnaires Web-based self-report questionnaires based on well established instruments. Focus Group Interviews Group conversation with open-ended questions with 7-10 students/ group on topics relevant to the aim of the study.

Outcome Measures

Primary Outcome Measure:

1. Mental health problems and pain
   Repeated measures with web-based questionnaires, 5 times (every 3 months),over one academic year.Outcomes will be measured with the Depression Anxiety Stress Scales-21 (DASS-21) [21]. The DASS-21 includes three subscales designed to measure depression, anxiety and stress symptoms in nonclinical populations. Musculoskeletal pain will be measured with the The Nordic Musculoskeletal Questionnaire. Weekley SMS (text messages) measure levels of pain, anxiety and depression.

   [Time Frame: 2019-2022]

Secondary Outcome Measure:

2. Mental health problems and pain related to the Covid-19 pandemic
   Web-based questionnaires comparing students entering the study before the onset of the Covid-19 pandemic and after. Outcomes will be measured with the Depression Anxiety Stress Scales-21 (DASS-21) [21]. The DASS-21 includes three subscales designed to measure depression, anxiety and stress symptoms in nonclinical populations. Musculoskeletal pain will be measured with the The Nordic Musculoskeletal Questionnaire. Weekley SMS measure levels of pain, axiety and depression.

   [Time Frame: 2019-2020]

Eligibility

Study Population:	University students attending selected universities in Stockholm, Sweden. A number of universities are included representing different educational programs such as medicine and life sciences, business, social sciences and technology. There is a majority of student from medical. and life science educational programs. The aim is to include a total of 5000 students.
Sampling Method:	Non-Probability Sample
Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	Yes All students invited to participate in the study answer the question about gender identity - female, male or other. All analyses with regard to gender in the study are based on self-representation based on these three categories.
Accepts Healthy Volunteers:	

Criteria: Inclusion Criteria:

The inclusion criteria are students at selected universities/colleges in the Stockholm attending selected educational programs with at least one remaining academic year before graduating. Students from matriculation to master level studies are invited to participate. Participants need to be 18 years of age or older, have access to a smart phone, laptop or tablet and speak sufficient Swedish or English.

NOTE : Preferred format includes lists of inclusion and exclusion criteria.

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IPDSharing

Plan to Share IPD: Undecided
Parallell studies in Norway and Canada have been planned for cross-cultural comparisons with merged data sets.

References

Citations:

Links:

Available IPD/Information:

Documents

Informed Consent Form
Document Date: August 19, 2019
Uploaded: 06/09/2020 15:40