TELEMONITORING AND AI FOR MENTAL HEALTH ASSESSMENT

General Objective:

To carry out a comparative and mutimodal analysis of the effectiveness in assessing anxiety and depression between three different devices: the FACS system from the company DYAGNOSYS, the CardioWatch 287 bracelet from the company CORSANO and the validated questionnaires used as a reference. The research aims to compare the accuracy and reliability of screening devices and validated questionnaires in the diagnosis of anxiety and depression.

Suggestion to rewrite the general and specific objectives, after analyzing the description of the Methodology.

To verify the accuracy and reliability of screening devices - the FACS system from DYAGNOSYS and the CardioWatch 287 bracelet from CORSANO - in diagnosing anxiety and depression in relation to validated questionnaires used as a reference.

Specific objectives:

- To compare the accuracy and reliability of multimodal screening devices and validated questionnaires in the assessment and diagnosis of anxiety and depression;
- Assess whether the devices can be easily integrated into clinical contexts of the assessment of mental disorders, considering costs, ease of use and the training required for use,
- Check the acceptance of the devices by the participants.

RESEARCH METHODOLOGY

1. Sample size:

The sample size was calculated using the OpenEpi® program version 3.01, using the equation: $n = [DEFF*Np(1-p)]/ [(d /Z^{2}_{1-\alpha/2} *(N-1)+p*(1-p)]$, where: N = Population size (for the finite population correction factor or fcp); p = Hypothetical % frequency of the outcome factor in the population; EDFF = Design effect for group surveys and d = Confidence limits as % of 100 (absolute +/-%).

The calculation used a population of 636 medical students, an anticipated frequency of the outcome of 50% (hypothetical), a margin of error of 5%, a design effect of 1.0 and a 95% confidence interval. In view of these parameters, according to the results of the OpenEpi® program, a sample of **240** medical students to be surveyed was calculated.

2. Sample selection:

All students regularly enrolled in the Medicine course at the UNIVÉRTIX University Center will be invited to take part in the study by means of an invitation letter sent via e-mail. Participation will be conditional on students filling in a virtual form to formally express their interest. A minimum of 240 students who have signed the Informed Consent Form (ICF) will be accepted to begin the study.

Inclusion criteria: regularly enrolled students over the age of 18
Exclusion criteria: students under the age of 18, having experienced a significant stressor in the week prior to the application of the anxiety and depression instrument(s).

For this multicenter study, we suggest that the sample used by our partner in Switzerland should also be made up of medical students.

The selection of this sample is based on the growing number of cases of depression and anxiety among medical students, which has been widely documented in global studies. Consistent data suggests that these conditions can lead to serious consequences, such as substance abuse, dropping out, neglecting one's own health and, in more extreme situations, suicide, which underscores the importance of addressing mental health needs in universities.

We emphasize that, in a second stage of validation of the application, this research will be carried out with children and adolescents.

3. Validation questionnaires:

Of the existing scales for assessing changes in mood, the 21-item Depression, Anxiety and Stress Scale (DASS-21) has been translated into several languages and is the subject of a number of validation studies.

The DASS-21 is a self-report scale containing a set of three subscales made up of seven items, aimed at assessing the emotional states of depression, anxiety and stress. There are four possible responses in terms of severity or frequency, organized in a Likert-type scale made up of a set of phrases (items) and, for each of them, the subject being assessed is asked to express the degree of agreement from "Strongly disagree", whose score is zero, to "Strongly agree", whose score is three.

The result is obtained by adding up the scores of the items for each of the three sub-scales.

Other scales, validated in both English and Portuguese, which assess anxiety and depression separately, are listed below.

Anxiety screening questionnaires:

Generalized Anxiety Disorder Scale (GAD-7)
→ was developed by Spitzer et al. (2006) with the

with the aim of being a brief self-report instrument for identifying probable cases of generalized anxiety disorder or excessive anxiety.

This scale is originally made up of seven items, arranged on a four-point Likert scale (0 = not at all, 1 = several days, 2 = more than half the days and 3 = almost every day), where the score can vary from 0 to 21. Thus, the level of anxiety is estimated using the following classification: 0-4 as minimal, 5-9 mild, 10-14 moderate and 15-21 severe, with a score above 10 indicating the significant presence of anxious symptoms.

Beck *Anxiety Inventory* (BAI) → this is a self-report scale that measures the intensity of anxiety symptoms. The BAI is made up of 21 items that are "descriptive statements of anxiety", which must be evaluated by the individual with reference to themselves on a four-point scale that reflects levels of increasing severity of each symptom: 1 = absolutely not; 2 = slightly: it didn't bother me much; 3 = moderately: it was very unpleasant, but I could bear it; 4 = severely: difficult to bear.

The scale reflects somatic, cognitive and affective manifestations characteristic of anxiety and refers to the symptoms that have bothered the individual in the last week, and can range from 0 to 63. The level of anxiety is classified as normal anxiety when the total score ranges from 0 to 9 points, anxiety of mild to moderate when the total score is between 10 and 18 points, moderate to severe anxiety when it ranges from 19 to 29 points and severe anxiety between 30 and 63 points.

Questionnaires for depression screening:

Patient Health Questionnaire-9 **(PHQ-9)** → derived from the *Primary Care Evaluation of Mental Disorder* (PRIME-MD), which was originally developed to identify common mental disorders in primary health care: depression, anxiety, alcohol abuse, somatoform disorders and eating disorders. The PHQ-9 is characterized by being a relatively quick-to-apply instrument, containing nine questions that assess the presence of each of the symptoms for an episode of major depression described in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). It is advantageous for epidemiological studies due to its simplicity and effectiveness, and is one of the most popular tools used worldwide to screen for depression.

In this questionnaire, the frequency of each symptom in the last two weeks is assessed on a Likert scale from 0 to 3, corresponding to the answers "not at all", "several days", "more than half the days" and "almost every day", respectively. The questionnaire also includes a tenth question that assesses the interference of these symptoms in the performance of daily activities, such as working and studying.

The total score ranges from 0 to 27 and represents the sum of the answers to the nine items. The severity of the condition would be estimated according to the following score: 0-4 points - no depression; 5-9 points - mild depressive disorder; 10-14 points - moderate depressive disorder; 15-19 points - moderately severe depressive disorder and from 20 to 27 points - severe depressive disorder.

Beck Depression Inventory (BDI) → highly regarded for depression screening. It features 21 questions, each with four possible answers. The BDI is more detailed than the PHQ-9 and covers a wider range of symptoms, which can be beneficial for assessing depressive symptoms more thoroughly.

The BDI version II has been validated for Portuguese and consists of 21 questions about depressive symptoms in the last 15 days that are rated on an ordinal scale from 0 to 3, producing total scores ranging from 0 to
63. The suggested limits for the levels of severity are: 0-13, minimal/none depression; 14-19, mild depression; 20-28, moderate depression; and 29-63, severe depression.

Hamilton Depression Rating Scale (HAM-D) → frequently used in psychiatric settings and requires a specialized, trained professional to administer, and is considered the gold standard for assessing changes in depression severity over time, particularly in research settings.

The most widely used version of the HAM-D is made up of 17 questions referring to the symptoms of depression experienced in the last week, which are classified on a scale of 0 to 4. Scores of 0 to 7 are considered normal, 8 to 16 suggest mild depression, 17 to 23 moderate depression and scores above 24 are indicative of severe depression.

In the validation study for Portuguese, a score of 9 was considered a satisfactory cut-off point, giving the instrument a sensitivity of 0.90 and specificity of 0.91. This result means that the test has a 90% chance of correctly identifying individuals with depression.

4. Operation of the FACS System - DYAGNOSYS:

The software is designed to analyze facial expressions from video recordings to assess emotional states related to stress, anxiety and depression. It uses the **Facial Action Coding System** (FACS) to quantify specific movements of the facial muscles, known as Action Units (AUs), which are linked to these emotional states.

How Facial Recognition works:

a. Video Input and Processing

The software accepts video files as input, capturing facial expressions over time. It processes the video frame by frame

to analyze temporal changes in facial expressions. Each frame is analyzed to detect the presence of a face using computer vision techniques and the detected facial images are standardized to ensure consistency in the analysis (for example, by adjusting lighting and orientation).

b. Prediction of Action Units

The software examines facial landmarks such as eyebrows, eyes and mouth to identify subtle muscle movements, quantifying the intensity of specific Action Units (AUs) associated with stress, anxiety and depression.

c. Facial Action Coding System (FACS)

FACS is a comprehensive system for categorizing facial movements based on muscle activity. Each Action Unit (AU) corresponds to a specific facial muscle or group of muscles (for example, AU4 is the "Eyebrow Lowerer"). Certain AUs have been empirically linked to emotional states, allowing for an objective assessment.

Presentation of results:

a. Processed Board Display

The software displays a processed image of the video (typically the last frame analyzed) to show the evaluated facial expression. The image can include markers highlighting key facial features or analyzed muscle movements.

b. Emotional State Scores

The results include graphical representations showing scores for stress, anxiety and depression with scores ranging from 0 to 1 to provide a standardized measure of emotional intensity. Higher scores indicate a greater presence of facial expressions associated with the corresponding emotional state.

c. Intensities of Action Units

A second graph displays the average intensities of each relevant AU. The AUs are labeled with their number and a brief description for clarity. This detailed information allows clinicians to understand which specific facial movements contribute to the overall emotional state scores.

Emotion Scores

a. Selection of Relevant Action Units

Dyagnosys intellectual property

b. Calculation of AU Intensities

Dyagnosys intellectual property

c. Calculating the Emotion Score

Dyagnosys intellectual property

Capturing and evaluating facial expressions:

a. Capture process

When analyzing each frame, the software monitors facial expressions throughout the duration of the video. It takes into account variations in the

head, lighting and facial orientation to maintain accuracy.

b. Evaluation Methodology

The software uses quantifiable data, such as the intensities of AUs, instead of relying on subjective interpretations, taking into account the consistency and duration of expressions, essential elements in assessing emotional states. In this way, it summarizes complex data on facial movements into scores and interpretable visual representations.

c. Reliability and Validity Considerations

Averaging intensities over multiple frames minimizes the impact of momentary facial movements that don't reflect emotional states. By focusing on AUs scientifically associated with stress, anxiety and depression, the software increases the accuracy of its assessments. Thus, the objective data generated can complement both clinical observations and patient reports.

Clinical Implications

The software therefore provides a way of assessing emotional states without the need for self-reporting, which can be influenced by stigma or reluctance. It can be used in settings where continuous emotional assessment is beneficial, such as therapy sessions or stress tests. The insights gained from analyzing facial expressions can assist in diagnosing emotional disorders and monitoring treatment progress.

5. Evaluation of Communication Communication:

In the academic context, Non-Verbal Communication (NVC) is understood as any form of communication beyond what is said or written. It manifests itself through signs such as gestures, facial expressions, body posture, tone of voice, eye contact, physical proximity, touch, objects, clothing and the use of the surrounding space. CNV can modify, reinforce or contradict verbal messages and its analysis contributes significantly to the assessment of stress and anxiety levels.

The app used to recognize facial expressions is also capable of analyzing **specific gestures** and **vocal characteristics** related to stress and anxiety. The images and audio captured by the device's cameras and microphones are examined using signal processing techniques and machine learning models that generate a stress score from the frequency and intensity of vocal patterns and body gestures, allowing for a more comprehensive analysis of the individual's emotional state.

Parameters analyzed:

Laying analysis:

- Tension: Stiff or tense posture can indicate stress.

○ Closed positions: Crossing the arms or legs can be a mechanism
defensive.
○ Slouching: Slouching can reflect low energy or anxiety.

Gesture and Movement Analysis:

○ Restlessness: Repetitive movements such as tapping your fingers or shaking your hands.
legs signal nervousness.
○ Touching the Face or Neck: Frequent touching can be a self-injurious action.
calms down under stress.
○ Walking from one side to the other: Walking from one side to the other can
indicate agitation.

Eye contact analysis

○ Avoidance: Lack of eye contact can reflect discomfort or anxiety.
○ Rapid blinking: This may indicate stress or information overload.
○ Staring: Intense staring can be a sign of aggression or high stress.

Analysis of breathing patterns:

○ Rapid breathing: Associated with panic or high anxiety.
○ Sighs: Frequent sighs can indicate frustration or exhaustion.

Analysis of vocal characteristics:

○ Tone Variation: Increased tone can indicate tension.
○ Rate of speech: Speaking too quickly or too slowly can be a sign of stress.
○ Volume changes: Speaking quieter or louder than usual.
○ Voice tremors: Voice tremors reflect nervousness.

Analysis of oral language and content:

○ Choice of Words: Use of negative or anxious language.
○ Disfluencies: Increase of words such as "ah", "um" or
stuttering.
○ Sentence Structure: Fragmented or too long sentences.

Analysis of Pauses and Silences:

○ Prolonged pauses: They can indicate hesitation or uncertainty.
○ Interruptions: Shutdowns e frequent restarts may reflect overload
cognitive.

6. How it works of the CORSANO CardioWatch Bracelet 287:

The **Corsano CardioWatch** bracelet will be used to monitor the patient's vital signs during the questionnaires and to capture images with the FACS software.

287. This device allows you to set data collection intervals per minute, per second or
25 Hz, 32 Hz and 128 Hz and continuously measures heart rate, oxygen saturation, respiratory rate, body temperature, activity tracking and sleep. The data collected by the bracelet is automatically sent to a Health Cloud, under the responsibility of the Swiss company CORSANO. This device is currently widely used for monitoring

continuous monitoring of patients in both inpatient and outpatient settings, with specific applications in the areas of cardiology and oncology, providing a detailed and accurate view of the main physiological parameters.

7. Data analysis:

After applying the standard questionnaires to assess anxiety and depression, the sample will be separated into 2 groups for analysis:

GROUP 1: Students diagnosed with anxiety and depression using the standard questionnaire.
GROUP 2: Students who were not diagnosed with depression or anxiety using the standard questionnaire.

Based on these results, the data will be cross-checked with the data obtained from the telemonitoring carried out by the DYAGNOSYS FACS application (test device 1) and the CORSANO vital signs assessment bracelet (test device 2).

Cases diagnosed with anxiety and depression using the standard instruments will be referred to UNIVÉRTIX's psychology clinic.
The results of test devices will not be considered for diagnosis.

8. Expected results of the study:

The FACS (DYAGNOSYS) and CardioWatch 287 test devices are expected to
(CORSANO) show a good correlation with validated questionnaires, which are used as a standard in the diagnosis of depression and anxiety. The study can also assess whether the devices can be easily integrated into clinical contexts, considering costs, ease of use and training required for use, offering a more robust and effective approach to assessing mental disorders. The research could also verify the acceptance of the devices by the participants.

9. Data storage:

The data collected will be stored in the DYAGNOSYS database, encrypted and protected with an access key.

Reference
https://www.mdpi.com/1424-8220/19/17/3693