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Mobile Application (Virtusan), a science-based habit formation educational digital tool for empowerment of healthier lifestyle, optimum nutritional habits, physical & mental health, sleep status, and quality of life. The VIRTUSAN Clinical Trial.

Submission date 03/07/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 04/12/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/12/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Studies have revealed that despite medical advancements, the overall quality of life and health status in the modern era are estimated to be low. Contributing factors include lack of exercise, unhealthy diet, high stress levels, and sleeping disorders, leading to an increased prevalence of diseases such as cardiovascular diseases, cancer, diabetes, hypertension, and metabolic syndrome. This has strained healthcare providers, negatively impacting the economy and healthcare policies. While various methods have been used to minimize risk factors and reduce disease frequency, their effectiveness remains uncertain. Physicians commonly rely on pharmaceutical drugs, but their side effects, limited efficacy, and potential addiction can adversely affect health status, quality of life, and longevity. Digital applications offer a potential alternative to improve health risk factors, prevent diseases, reduce sudden cardiac death risk, and enhance longevity and quality of life. The Virtusan application is a unique habit formation software focusing on mental fitness, sleep, nutrition, and physical fitness. It aims to improve dietary habits, sleep patterns, and overall well-being. By reducing disease burdens, the application could be a non-invasive, cost-effective tool benefiting healthcare systems. This study aims to evaluate the effectiveness of the Virtusan mobile application in enhancing sleep quality, mood, stress levels, dietary habits, physical exercise, and mental health in healthy adults, particularly medical students. It will assess the correlation between app usage and improvements in various health parameters, including biochemical, clinical, physical, and mental indicators. The ultimate goal is to decrease disease risk, improve quality of life, and enhance longevity rates by embracing the holistic approach of the Virtusan mobile application.

Who can participate?
Medical students aged 18 to 40 years old

What does the study involve?
Medical students will be assigned to use the Virtusan application for 4 months (Group A) or are not use the application (Control Group). Before and after the period of the 4 months in both of the groups, biochemical blood tests, clinical parameters, stress, quality of life scores and sleep quality test are going to reveal any potential statistically significant difference in the already mentioned parameters in the same group (before and after the use of application in Group A and in Control group) and between the groups (A and the Control group).

General evaluation indexes were chosen to investigate any possible improvement in health-related parameters from the use of the application (before and after the use of the application-between group to-group model and between control group and study group model), including blood pressure, heart rate, body mass index, hematological and biochemical blood exams, diabetes biochemical profile, renal function biochemical profile, risk of cardiovascular disease biochemical profile, liver and bile duct function biochemical profile, nutritional status biochemical profile and hormonal biochemical profile. Sleep quality and anxiety will be measured using questionnaires.

What are the possible benefits and risks of participating?
The use of the Virtusan application for 4 months probably will reduce blood pressure and heart rate frequency, providing evidence that expanding longevity is possible with digital application guidance since lower blood pressure and lower heart rate frequency are correlated with lifespan extension. Additionally, the sleep digital engineering provided by the pillar of the virtusan application, could improve the quality of sleep and so permit neurons to have access to the necessary oxygenation time, to repair brain damage due to stress and due to daily activities. Mood and anxiety are two important components of mental health and both of them, after the use of the relative application, possibly they are going to be improved, playing a crucial role in the protection from neurodegenerative diseases. Regarding the biochemical background reflection, the daily use of the Virtusan application may be correlated positively with the improvement of biochemical and haematological parameters.

Where is the study run from?
AHEPA University Hospital (Greece)

When is the study starting and how long is it expected to run for?
May 2022 to April 2023

Who is funding the study?
Aristotle University of Thessaloniki (Greece)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
VIRTUal Simulator mobile ApplicatioN (VIRTUSAN), a promising and challenging educational tool for digital health empowerment. A four-dimensional pillar implementation journey for optimum cardiometabolic lifestyle and quality of life, implementing nutritional, physical, mental and sleep habits. The VIRTUSAN Clinical Trial.

Acronym
VIRTUSAN

Study objectives
A variety of methods have been used in the past to minimize the impact of risk factors on health and so to reduce the frequency of diseases, nevertheless, the results are debated. In particular, the most common practice from physicians to treat and limit the risk factors is mainly based on pharmaceutical molecules, but side effects, short-term and long-term efficacy, and biological and psychological addiction due to chronic use of drugs are considerable factors affecting negative health status, quality of life and longevity.

Digital applications can potentially be used as an alternative and effective method to improve health risk factors, prevent future diseases, reduce sudden cardiac death risk and increase longevity and quality of life. Virtusan application is a unique habit formation software that interacts with the user in four predefined “pillars” of health-related parameters (nutritional, physical, mental and sleep habits). Focusing on improving dietary habits, sleep patterns and physical and mental health, Virtusan application can be used as an alternative, noninvasive, and cost-effective tool, to reduce the burden of diseases, providing a multidimensional positive impact on the economic sustainability of the health care systems of the different countries. The potential of the Virtusan application has now been tested on the health status of medical students for a period of 6 months, reflecting vital changes in biochemical, clinical, physical and mental parameters.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/06/2022, Bioethics and ethics Committee of the Aristotle University Thessaloniki (Faculty of Health Sciences, Medical Department, New Amphitheatres, School of Medicine, Thessaloniki, 541 24, Greece; +30 2310 999338; bioethics@med.auth.gr), ref: 6/14.6.2022

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital, Laboratory, Training facility/simulation, University/medical school/dental school

Study type(s)
Diagnostic, Prevention, Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Prevention of cardio metabolic diseases, improving life style, health care economical systems sustainability (national and public) improvement, empowerment of digital health artificial intelligent algorithms, decrease of the future mortality and morbidity rate in health care systems using the artificial inteligent digital health by distance.

Interventions

Using the application in a four-dimensional pillar educational digital tool (nutrition, physical, mental and sleep patterns habits).

The population of the study is composed of 30 medical students that are going to use the Virtusan application for 4 months (Group A) and 30 medical students that are not going to use the application (Control Group). Before and after the period of the 4 months in both of the groups, biochemical blood tests, clinical parameters, stress, quality of life scores and sleep quality tests are going to reveal any potential statistically significant difference in the already mentioned parameters in the same group (before and after the use of the application in Group A and in Control group) and between the groups (A and the Control group).

General evaluation indexes in order to investigate any possible improvement in health-related parameters from the use of the application (before and after the use of the application-between group to-group model and between the control group and study group model), selected for the study are the following:
1. Blood pressure: a normalized sphygmomanometer is going to be used for the evaluation of systolic and diastolic blood parameters. The measurements took place with the subject in a sitting position for 5 minutes, in a quiet environment with a stable temperature of 25 C. The index of improvement will be the average difference between systolic and diastolic blood pressure before and 4 months after the use of the application (the t-test method will be used for statistical significance difference between the before and after the period).
2. Heart rate frequency average: The measurements took place using an oximeter with the subject in a sitting position for 5 minutes, in a quiet environment with a stable temperature of 25 C.
3. Pittsburgh Sleep Quality Index (PSQI): a self-report questionnaire with 19 items (scale range = 0 - 21). Higher scores indicate more sleep problems and a score > 5 separates poor sleepers from good sleepers. The PSQI has good psychometric properties, and it is recommended as an essential outcome measure in sleep studies.
4. EQ-5D: a standardized score for health-related quality of life estimation, developed by the EuroQol Group, in order to provide a simple, generic questionnaire for use in clinical and economic appraisal and population health surveys. EQ-5D assesses health status in terms of five dimensions of health and is considered a ‘generic’ questionnaire because these dimensions are not specific to any one patient group or health condition.
5. Profile of Mood States (POMS): a well-established measure of psychological distress derived from factor analysis, and its high levels of reliability and validity have been documented. This questionnaire contains 65 words/adjectives that describe several aspects of mood that are grouped into the following six subscales: tension, depression, anger, vigor, fatigue and confusion. The vigor subscale refers to a positive state of mind, and the other factors, to a negative state of mind. Each item is valued following a Likert type format, with five response alternatives: not at all (0), a little (1), moderately (2), quite a bit (3) or extremely (4). The subscales are combined for a total mood score.
6. The State-Trait Anxiety Inventory (STAI): a psychological inventory consisting of 20 self-report items on a 4-point Likert scale. The STAI measures two types of anxiety – state anxiety (Y1 version) and trait anxiety (Y2 version). The Trait Anxiety Inventory is widely used to measure

anxiety symptoms. Trait anxiety items assess how subjects generally feel. Total scores range from 20 to 80. STAI scores are commonly classified as low anxiety (scoring 20-37), moderate anxiety (scoring 38-44), and high anxiety (scoring 45-80).
7. Anthropometric measurements: body mass index variability.
8. Hematological and biochemical blood exams: white blood cell count (WBC), red blood cell count (RBC), platelet count, hematocrit red blood cell volume (HCT), hemoglobin concentration (HB), white blood and red blood cell volume and general indices.
9. Diabetes biochemical profile: level of glucose (blood sugar) and HbA1c reflex panel in cases of high blood sugar (non-fasting assessment)
10. Renal function biochemical profile: urea, creatinine, eGFR (calculation of glomerular filtration rate), uric acid, phosphorus
11. Gout biochemical profile: uric acid bone health biochemical profile: calcium, phosphorus, alkaline phosphatase (ALP)
12. Risk of cardiovascular disease biochemical profile: cholesterol, triglycerides, HDL and LDL cholesterol, apolipoprotein B (if triglyceride level is too high)
13. Liver and bile duct function biochemical profile: total bilirubin, ALP, lactate dehydrogenase (LDH), aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyltransferase (GGT), albumin nutritional status biochemical profile: Na, K, Cl, proteins, albumin, globulin, albumin/globulin (A/G) ratio, LDH
14. Hormonal biochemical profile: Thyroid function, nutritional and vitamin status.

Intervention Type
Behavioural

Primary outcome measure
The following primary outcome measures will be assessed before and 4 months after the use of the application:
1. Blood pressure measured using a normalized sphygmomanometer
2. Heart rate frequency was average measured using an oximeter
3. Sleep problems measured using the Pittsburgh Sleep Quality Index (PSQI)
4. Health-related quality of life measured using the EuroQol EQ-5D
5. Mood measured using the Profile of Mood States (POMS)
6. Anxiety measured using the State-Trait Anxiety Inventory (STAI)

Secondary outcome measures
1. Anthropometric measurements: body mass index variability with Height and Weight Scale and BMI digital calculator, before and 4 months after the use of the application
2. Hematological & Biochemical blood exams: white blood cell count (WBC), red blood cell count (RBC), platelet count, hematocrit red blood cell volume (HCT), hemoglobin concentration (HB), white blood and red blood cell volume and general indices with Hematology Analyzer of AHEPA University Bio Lab, before and 4months after the use of the application
3. Diabetes biochemical profile: level of glucose (blood sugar) and HbA1c reflex panel in cases of high blood sugar (non-fasting assessment) measured using a Biochemistry analyzer of AHEPA University Bio Lab, before and 4 months after the use of the application
4. Renal function biochemical profile: urea, creatinine, eGFR (calculation of glomerular filtration rate), uric acid, phosphorus Gout biochemical profile: uric acid bone health biochemical profile: calcium, phosphorus, alkaline phosphatase (ALP) risk of cardiovascular disease biochemical profile: cholesterol, triglycerides, HDL and LDL cholesterol, apolipoprotein B (if triglyceride level is too high) measured using a Biochemistry analyzer of AHEPA University Bio Lab, before and 4 months after the use of the application
5. Liver and bile duct function biochemical profile: total bilirubin, ALP, lactate dehydrogenase

(LDH), aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyltransferase (GGT), albumin nutritional status biochemical profile: Na, K, Cl, proteins, albumin, globulin, albumin/globulin (A/G) ratio, LDH Hormonal biochemical profile: Thyroid function, nutritional and vitamin status measured using a Biochemistry analyzer of AHEPA University Bio Lab, before and 4 months after the use of the application

Overall study start date
10/05/2022

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Medical students
2. Aged 18 to 40 years old
3. Males and females
4. Ability to use an application
5. Familiarity with the completion of clinical trials questionnaires
6. Mentally and physically healthy
7. Familiarity with artificial intelligence

Participant type(s)
Learner/student

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Unfamiliar with the use of applications
2. Mental or physical disease
3. >40 years old
4. Not a medical student

Date of first enrolment
01/09/2022

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
Greece

Study participating centre
AHEPA University Hospital
1st Propedeutical University Department of internal medicine
Aristotle University of Thessaloniki
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Organisation
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Sponsor type
University/education

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ROR
https://ror.org/01q1jaw52

Funder(s)

Funder type
University/education

Funder Name
Aristotle University of Thessaloniki

Alternative Name(s)
Aristotelian University, University of Thessaloniki

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Greece

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed Journal

Intention to publish date
15/12/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available due to copyright and GDPR restrictions.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			01/12/2023	No	No