

DIGITAL APPARATUS AND APPLICATION FOR MYOPIA THERAPY

[0001] CROSS-REFERENCE TO RELATED APPLICATION

[0002] This application claims under 35 U.S.C. §19(a) priority to and the
5 benefit of Korean Patent Application No. 10-2019-0130146, filed October 18,
2019, the disclosure of which is incorporated herein by reference in its
entirety.

BACKGROUND

10 [0003] Technical Field

[0004] The present invention relates to digital therapeutics (hereinafter
referred to as DTx) intended for myopia therapy, which includes inhibition of
progression of myopia. In particular, it encompasses deducing a
mechanism of action (hereinafter referred to as MOA) in axial myopia in
15 childhood/adolescence stages through the literature search and expert
reviews of basic scientific articles and related clinical trial articles to find the
mechanism of action in myopia, and establishing a therapeutic hypothesis
and a digital therapeutic hypothesis for inhibiting progression of axial myopia
in the childhood/adolescence stages and treating the axial myopia based on
20 these findings.

[0005] Also, the present invention relates to a rational design of an
application for clinically verifying a digital therapeutic hypothesis for axial
myopia in the childhood/adolescence stages and realizing the digital
therapeutic hypothesis for digital therapeutics, and to the provision of a digital
25 apparatus and an application for inhibiting progression of axial myopia in

childhood/adolescence stages and treating the axial myopia based on this rational design.

(b) Background Art

5 **[0006]** In Korea, myopic patients have very high morbidity. The results of data analysis in the years 2008 to 2012 show that the morbidity of myopia (-0.75 diopters or higher) in 12- to 18-year-old adolescents in Korea is 80.4%, which is 4.35 times higher than the morbidity of myopia (18.5%) in the 60-year-old elderly in demographic aspects, and that the morbidity in high
10 myopia (-6 diopter or higher) is 12%, which is 8 times higher than that of the 60-year-old elderly (1.5%), and also is three times higher than the morbidity of myopia of the adolescents in U.S.A, the United Kingdom , etc.

[0007] It is more serious that approximately 70% of the adolescent myopic patients in Korea were surveyed to be medium- and high-myopic patients.
15 Also, the morbidity of myopia in the elementary school students was approximately 23% in 1980, but steadily increased from 38% in 1990 to 46.2% in 2000.

[0008] The World Health Organization (WHO) has recognized myopia as one of diseases, but there is no potent therapeutics against myopia around
20 the world. In recent years, the myopia began again to receive academic attention as the morbidity of myopia has increased suddenly in China, Singapore, Korea, etc. Also, the myopia has emerged as an ophthalmologic disease that may also cause the loss of eyesight in the future.

[0009] Types of myopia are divided into axial myopia caused due to the
25 extending axis of eyeball and refractive myopia (i.e., indexmyopia) caused

due to an increased refractive index of the eye lens or the cornea, etc. Types of the axial myopia are divided into simple myopia having no influence on the retina or the choroid, and degenerative myopia causing deformation in the retina to induce the loss of eyesight. Except for nuclear sclerosis and
5 keratoconum caused by the diabetes, most of the myopia corresponds to simple axial myopia whose progression is accelerated from the elementary school ages.

[0010] As this method for delaying progression of or treating myopia, a method of using a drug (atropine) and a special lens (for example, a dream
10 lens) was known. However, atropine causes serious dazzling with the pupil dilation. Also, because the dream lens has a high risk of damage to the cornea, it has limited clinical applications, compared to glasses for vision corrosion.

[0011] Separately, although a variety of apparatuses for treating myopia,
15 eye exercise methods, eye exercise applications, and the like have been developed and sold in the market, most of them have insufficient grounds for the clinical efficacy, and are sold without any additional permission. However, there is no highly reliable therapeutic method that the childhood/adolescent patients who have been diagnosed as myopia in the
20 hospitals can use to inhibit progression of and treat myopia.

SUMMARY OF THE DISCLOSURE

[0012] First of all, according to the present invention, a mechanism of action in myopia, and a therapeutic hypothesis and a digital therapeutic
25 hypothesis for myopia are deduced in consideration of an eye development

stage according to the childhood/adolescent growth and neurohumoral factors for progression of myopia. Therefore, an object of the present invention is to provide a digital apparatus and an application for treating myopia whose reliability may be ensured, which can inhibit progression of myopia and provide a therapeutic effect by allowing a patient to repeatedly execute digital instructions under a light stimulus environment based on a digital therapeutic hypothesis for myopia.

[0013] According to one embodiment of the present invention, there is provided a digital apparatus for treating myopia, which includes a digital instruction generation unit configured to generate a digital therapeutics module for treating myopia based on the mechanism of action in and therapeutic hypothesis for the myopia, generate specified digital instructions based on the digital therapeutics module, and provide the digital instructions to a first user; and an outcome collection unit configured to collect the first user's execution outcomes of the digital instructions.

[0014] According to another embodiment of the present invention, there is provided a digital application for treating myopia capable of instructing a computing apparatus to execute operations, which includes generating a digital therapeutics module for treating myopia based on a mechanism of action in and a therapeutic hypothesis for the myopia; generating specified digital instructions based on the digital therapeutics module; providing the digital instruction to a first user; and collecting the first user's execution outcomes of the digital instructions.

EFFECT OF THE DISCLOSURE

[0015] According to the digital apparatus and the application for treating axial myopia according to the present invention, a reliable digital apparatus and application capable of inhibiting progression of and treating myopia may be provided by deducing a mechanism of action in myopia and a therapeutic hypothesis and a digital therapeutic hypothesis for myopia in consideration of neurohumoral factors for progression of axial myopia, presenting digital instructions to a patient under suitable light stimulus environment setups based on the mechanism of action, the therapeutic hypothesis, and the digital therapeutic hypothesis, and collecting and analyzing execution outcomes of the digital instructions.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1A is a diagram showing a mechanism of action in axial myopia in the childhood/adolescence stages proposed in the present invention, FIG. 1B is a diagram showing a therapeutic hypothesis for the axial myopia proposed in the present invention, and FIG. 1C is a diagram showing a digital therapeutic hypothesis for axial myopia proposed in the present invention;

[0017] FIG. 2 is a block diagram showing a configuration of a digital apparatus for treating myopia according to one embodiment of the present invention;

[0018] FIG. 3 is a diagram showing input and output loops of a digital application for treating myopia according to one embodiment of the present invention;

[0019] FIG. 4 is a diagram showing a feedback loop for a digital apparatus and an application for treating myopia according to one embodiment of the present invention;

[0020] FIG. 5A is a diagram showing a module design for realizing a digital therapy in the digital apparatus and the application for treating myopia according to one embodiment of the present invention, FIG. 5B is a diagram showing a background factors supporting the digital apparatus and the application for treating myopia according to one embodiment of the present invention;

[0021] FIG. 6 is a diagram showing a method of assigning a patient-customized digital prescription using the digital apparatus and the application for treating myopia according to one embodiment of the present invention;

[0022] FIG. 7A shows execution environment setups according to one embodiment of the present invention, and FIGS. 7B to 7G show examples of specific instructions for each module, and methods of collecting output data according to one embodiment of the present invention;

[0023] FIG. 8 is a flowchart illustrating operations in a digital application for treating myopia according to one embodiment of the present invention;

[0024] FIG. 9 is a flowchart illustrating a method of generating digital instructions in the digital application for treating myopia according to one embodiment of the present invention;

[0025] FIG. 10 is a flowchart illustrating a method of repeatedly executing the operations under the feedback control in the digital application for treating myopia according to one embodiment of the present invention; and

[0026] FIG. 11 is a diagram showing a hardware configuration of the digital apparatus for treating myopia according to one embodiment of the present invention.

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DETAILED DESCRIPTION

[0027] Hereinafter, exemplary embodiments of the present invention will be described in detail. However, the present invention is not limited to the embodiments disclosed below, but can be implemented in various forms. The following embodiments are described in order to enable those of ordinary skill in the art to embody and practice the present invention.

[0028] While the invention has been shown and described with reference to certain exemplary embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

[0029] Although the terms first, second, etc. may be used to describe various elements, these elements are not limited by these terms. These terms are only used to distinguish one element from another. For example, a first element could be termed a second element, and, similarly, a second element could be termed a first element, without departing from the scope of exemplary embodiments. The term “and/or” includes any and all combinations of one or more of the associated listed items.

[0030] The singular forms “a,” “an” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise.

[0031] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of exemplary embodiments. With reference to the appended drawings, exemplary embodiments of the present invention will be described in detail below. To
5 aid in understanding the present invention, like numbers refer to like elements throughout the description of the figures, and the description of the same elements will be not reiterated.

[0032] In the prior art, the development of new drugs starts with confirming a medial demand *in situ*, proposing a mechanism of action based on the
10 expert reviews and meta-analysis on the corresponding disease, and deducing a therapeutic hypothesis based on the expert reviews and the meta-analysis. Also, after a library of drugs whose therapeutic effects are expected is prepared based on the therapeutic hypothesis, a candidate material is found through screening, and the corresponding candidate
15 material is subjected to optimization and preclinical trials to check its effectiveness and safety from a preclinical stage, thereby deciding the candidate material as a final candidate drug. To mass-produce the corresponding candidate drug, a CMC (chemistry, manufacturing, and control) process is also established, a clinical trial is carried out on the
20 corresponding candidate drug to verify a mechanism of action and a therapeutic hypothesis of the candidate drug, thereby ensuring the clinical effectiveness and safety of the candidate drug.

[0033] From the point of view of this patent, drug targeting and signaling, which fall upstream of the development of new drugs, have many
25 uncertainties. In many cases, because the drug targeting and signaling take

a methodology of putting together the outcomes, which have been reported in the art, and interpreting the outcomes, it may be difficult to guarantee the novelty of invention. On the contrary, the invention of drugs capable of regulating the drug targeting and signaling to treat a disease requires the
5 highest level of creativity except for the field of some antibody or nucleic acid (DNA, RNA) therapeutics in spite of the development of research methodology for research and development of numerous new drugs. As a result, the molecular structures of the drugs are the most critical factors that constitute the most potent substance patent in the field of new drugs.

10 **[0034]** Unlike the drugs whose rights are strongly protected through this substance patent, digital therapeutics are basically realized using software. Due to the nature of the digital therapeutics, the rational design of digital therapeutics against the corresponding disease, and the software realization of the digital therapeutics based on the rational design may be considered to
15 be a very creative process of invention to be protected as a patent when considering the clinical verification and approval processes as the therapeutics.

[0035] That is, the core of the digital therapeutics as in the present invention depends on the rational design of digital therapeutics suitable for
20 treatment of the corresponding disease, and the development of specific software capable of clinically verifying the digital therapeutics based on the rational design. Hereinafter, a digital apparatus and an application for treating myopia according to the present invention realized in this aspect will be described in detail.

[0036] FIG. 1A is a diagram showing a mechanism of action in axial myopia in the childhood/adolescence stages proposed in the present invention, FIG. 1B is a diagram showing a therapeutic hypothesis for the axial myopia proposed in the present invention, and FIG. 1C is a diagram showing a digital therapeutic hypothesis for axial myopia proposed in the present invention.

[0037] A digital apparatus and an application for inhibiting progression of and treating myopia according to the present invention as will be described below are realized based on the mechanism of action and therapeutic hypothesis deduced through the literature search and expert reviews of clinical trial articles on axial myopia in childhood/adolescence stages.

[0038] Generally speaking, disease therapy is carried out by analyzing a certain disease in terms of pathophysiological functions and dispositions in order to determine a start point, a progression point, and an end point for the disease. Also, an indication of the disease is defined by characterization of the corresponding disease and statistical analysis of the disease. Also, patient's physiological factors, especially neurohumoral factors, which correspond to the verified indications, are analyzed, and the patient's neurohumoral factors are restricted a narrow extent associated with the disease to deduce a mechanism of action.

[0039] Next, a therapeutic hypothesis, in which the corresponding disease is treated by controlling actions and environments directly associated with regulation of the corresponding neurohumoral factors associated with the disease, is deduced. To realize this therapeutic hypothesis into digital therapeutics, a digital therapeutic hypothesis for achieving a therapeutic effect through repeated digital instruction and execution, which are

associated with the “control of patient’s action/environment → regulation of neurohumoral factors, is proposed. The digital therapeutic hypothesis of the present invention is realized as a digital apparatus and an application is realized as a digital apparatus and an application configured to present
5 changes in patient’s actions (including behavioral, emotional, and cognitive areas), improvement of patient’s environment, and patient’s participation in the form of specific instructions and collect and analyze execution of the specific instructions.

[0040] Literature search for the clinical trials as described above may be
10 executed through meta-analysis and data mining, and the clinical specialist’s feedbacks and deep reviews may be applied in each analysis step. Basically, the present invention encompasses extracting a mechanism of action in and a therapeutic hypothesis for axial myopia using the procedure as described above, and regulating the neurohumoral factors based on these
15 results to provide a digital apparatus and an application as digital therapeutics for inhibiting progression of and treating axial myopia.

[0041] However, a method of extracting a mechanism of action in and a therapeutic hypothesis for axial myopia according to the present invention is not limited to the methods as described above. In addition, mechanisms of
20 action in and therapeutic hypotheses for diseases may be extracted using various methods.

[0042] Referring to FIG. 1A, various risk factors in the childhood/adolescence stages, for example, near working, education, race, genetics, and other factors (premature birth, diet, light exposure, birth season,
25 increased intraocular pressure, etc.) may cause the imbalance of

neurohumoral factors (which are related to the myopia onset) in the childhood/adolescence stages. As a result, proteoglycans are abnormally produced in the sclera around the eye due to IGF, cortisol, and dopamine dysregulation, which results in axial myopia developing due to abnormal growth of the optical axis.

[0043] Referring to FIG. 1B, the therapeutic hypothesis for axial myopia according to the present invention includes inhibition of progression of and treatment of axial myopia by restoring the balance of neurohumoral factors through the patient's actions (including behavioral, emotional, and cognitive areas) and environment, and the patient's participation.

[0044] Referring to FIG. 1C, the digital therapeutic hypothesis for axial myopia is realized as a digital apparatus and an application configured to present changes in patient's actions, improvement of patient's environment, and patient's participation in the form of specific instructions and collect and analyze execution of the specific instructions. When the digital therapeutics of the present invention are used, the imbalance of neurohumoral factors for axial myopic patients in the childhood/adolescence stages may be corrected through the digital inputs (instructions) and outputs (execution) to achieve inhibition of progression of and treatment of axial myopia.

[0045] Meanwhile, the mechanism of action in and the therapeutic hypothesis for axial myopia are described with reference to FIGS. 1A and 1B, but the present invention is not limited thereto. For example, the methodology of the present invention may be applied to all types of myopia, and any other diseases.

[0046] Also, although the insulin-like growth factor (IGF), cortisol, and dopamine are described as the neurohumoral factors as shown in FIGS. 1A and 1B, it should be understood that the description of the neurohumoral factors is given by way of illustration only, and are not intended to be limiting
5 in all aspects of the mechanism of action in and the therapeutic hypothesis for myopia according to the present invention. Accordingly, all the neurohumoral factors having an influence on the myopia may be considered.

[0047] FIG. 2 is a block diagram showing a configuration of the digital apparatus for treating myopia according to one embodiment of the present
10 invention.

[0048] Referring to FIG. 2, a digital system 000 for treating myopia according to one embodiment of the present invention may include a digital instruction generation unit 010, a sensing data collection unit 020, an execution input unit 030, an outcome analysis unit 040, a database 050, and
15 a security unit 060.

[0049] Based on the mechanism of action in and the therapeutic hypothesis and digital therapeutic hypothesis for axial myopia in the childhood/adolescence stages, a doctor (a second user) may prescribe digital therapeutics, which are realized in a digital apparatus and an application for
20 treating myopia, for the corresponding patient. In this case, the digital instruction generation unit 010 is a device configured to provide a prescription of the digital therapeutics to a patient as a specific behavioral instruction that the patient may execute based on the interaction between the neurohumoral factors for myopia and the patient's behaviors/environments.
25 For example, the neurohumoral factors may include IGF, cortisol, dopamine,

and the like, but the present invention is not limited thereto. For example, all types of neurohumoral factors that may cause myopia may be considered.

[0050] The digital instruction generation unit 010 may generate digital instructions based on the inputs from the doctor. In this case, the digital instruction generation unit 010 may generate digital instructions based on information collected by the doctor when diagnosing a patient. Also, the digital instruction generation unit 010 may generate digital instructions based on the information received from the patient. For example, the information received from the patient may include the patient's basal factors, medical information, and digital therapeutics literacy. In this case, the basal factors may include amount of the patient's activity, heart rates, sleep, meals (nutrition and calories), and the like. The medical information may include the patient's electronic medical record (EMR), family history, genetic vulnerability, genetic susceptibility, and the like. The digital therapeutics literacy may include the patient's accessibility and an acceptance posture to the digital therapy instructions and the apparatus, and the like.

[0051] The digital instruction generation unit 010 may reflect the mechanism of action in and the therapeutic hypothesis for myopia in order to utilize imaginary parameters and generate a digital module. In this case, the imaginary parameters may be deduced in term of the patient's environments, behaviors, emotions, and cognition. In this regard, the imaginary parameters will be described in detail as shown in FIG. 5.

[0052] The digital instruction generation unit 010 generates digital instructions particularly designed to allow a patient to have a therapeutic effect, and provides the instructions to the patient. For example, the digital

instruction generation unit 010 may provide light stimuli under a bright light environment, and simultaneously generate specific digital instructions in each of digital therapeutic modules.

[0053] The sensing data collection unit 020 and the execution input unit 5 030 may collect the patient's execution outcomes of the digital instructions provided at the digital instruction generation unit 010. Specifically, the sensing data collection unit 020 configured to sense the patient's adherence to the digital instructions and the execution input unit 030 configured to allow a patient to directly input the execution outcomes of the digital instructions 10 are included, and thus serve to output the patient's execution outcomes of the digital instructions.

[0054] The outcome analysis unit 040 may collect the patient's behavior adherence or participation in predetermined periods and report the patient's behavior adherence or participation to external systems. Therefore, a 15 doctor may continue to monitor an execution course of the digital instructions through the application even when a patient does not directly visit a hospital.

[0055] The database 050 may store the mechanism of action in myopia, the therapeutic hypothesis for myopia, the digital instructions provided to the user, and the user's execution outcome data. FIG. 2 shows that the 20 database 050 is included in the digital apparatus 000 for treating myopia. However, the database 050 may be provided in an external server.

[0056] Meanwhile, a series of loops including inputting the digital instructions at the digital instruction generation unit 010, outputting the patient's execution outcomes of the digital instructions at the sensing data 25 collection unit 020/execution input unit 030, and evaluating the execution

outcomes at the outcome analysis unit 040 may be repeatedly executed several times. In this case, the digital instruction generation unit 010 may generate patient-customized digital instructions for this cycle by reflecting the patient's digital instructions provided in the previous cycle and output values,
5 and the evaluation.

[0057] As described above, according to the digital therapy apparatus for inhibiting progression of and treating axial myopia according to the present invention, the myopia therapy whose reliability may be ensured is possible by deducing the mechanism of action in axial myopia and the therapeutic
10 hypothesis and digital therapeutic hypothesis for axial myopia in consideration of the neurohumoral factors for axial myopia, presenting the setups of light stimulus environments suitable for the patient and digital instructions for treating axial myopia based on the mechanism of action and the therapeutic hypotheses, and collecting and analyzing execution of
15 specific instructions.

[0058] FIG. 3 is a diagram showing input and output loops of the digital application for treating myopia according to one embodiment of the present invention.

[0059] Referring to FIG. 3, the digital application for treating myopia
20 according to one embodiment of the present invention may input the corresponding digital prescription for a patient in the form of instructions, and may output execution outcomes of the corresponding digital instructions.

[0060] The digital instructions provided to the patient may include specific action instructions for behaviors, emotions, cognition, and the like, and
25 control of the patient's light environments. As shown in FIG. 3, the digital

instructions may include eye exercise, reduced stress, a sense of accomplishment, light stimulus, and the like. However, the digital instructions are given by way of illustration only, and are not intended to be limiting to the digital instruction according to the present invention.

5 **[0061]** The patient's execution outcomes of the digital instructions consist of 1) log-in/log-out information for instructions and execution, 2) adherence information sensed as passive data such as eye exercise, heart rates associated with the stress, a change in oxygen saturation, and the like, and 3) directly input information on the patient's execution outcomes.

10 **[0062]** FIG. 4 is a diagram showing a feedback loop for the digital apparatus and the application for treating myopia according to one embodiment of the present invention.

[0063] Referring to FIG. 4, the inhibition of the progression of and the treatment of axial myopia are shown to be achieved by repeatedly executing
15 the aforementioned single feedback loop of FIG. 3 several times to regulate the neurohumoral factors.

[0064] In the case of the axial myopia, the digital therapy and observation take a short period of 10 weeks to the whole period of the childhood/adolescence stages to treat the axial myopia due to the
20 pathological characteristics of the axial myopia. Due to these characteristics, inhibitory and therapeutic effects on progression of the axial myopia may be more effectively achieved by gradual improvement of an instruction-execution cycle in the feedback loop, compared to the simply repeated instruction-execution cycle during the corresponding course of therapy.

[0065] For example, the digital instructions and the execution outcomes for the first cycle are given as input values and output values in a single loop, but new digital instructions may be generated by reflecting input values and output values generated in this loop using a feedback process of the loop to
5 adjust the input for the next loop when the feedback loop is executed N times. This feedback loop may be repeated to deduce patient-customized digital instructions and maximize a therapeutic effect at the same time.

[0066] As such, in the digital apparatus and the application for treating myopia according to one embodiment of the present invention, the patient's
10 digital instructions provided in the previous cycle (for example, a N-1st cycle), and the data on instruction execution outcomes may be used to calculate the patient's digital instructions and execution outcomes in this cycle (for example, a Nth cycle). That is, the digital instructions in the next loop may be generated based on the patient's digital instructions and execution
15 outcomes of the digital instructions calculated in the previous loop. In this case, various algorithms and statistical models may be used for the feedback process, when necessary.

[0067] As described above, in the digital apparatus and the application for treating myopia according to one embodiment of the present invention, it is
20 possible to optimize the patient-customized digital instructions suitable for the patient through the rapid feedback loop.

[0068] FIG. 5A is a diagram showing a module design for realizing a digital therapy in the digital apparatus and the application for treating myopia according to one embodiment of the present invention, FIG. 5B is a diagram
25 showing a background factors supporting the digital apparatus and the

application for treating myopia according to one embodiment of the present invention

[0069] As shown in FIG. 5A, when the therapeutic hypothesis based on the mechanism of action in myopia is created, targeted neurohumoral factors (for example, IGF, cortisol, dopamine, etc.) may be deduced. Imaginary parameters may be utilized to allow specific instructions to correspond to the regulation of these neurohumoral factors. Modules required to treat myopia was deduced using the “neurohumoral factor-imaginary parameter-module” interrelation. Each of the modules will be described in the form of modular instructions in further detail with reference to FIG. 7 as will be described below. In this case, each of the modules is in fact a basic design unit for digital therapeutics realized in the digital apparatus or the application, and is a collection of specific instructions.

[0070] Specifically, referring to FIG. 5A, the neurohumoral factors deduced based on the mechanism of action in and the therapeutic hypothesis for axial myopia may be IGF, cortisol (or TGF-beta influenced by the cortisol), and dopamine (or GABA agonist/antagonists, glucagon). To treat myopia, the neurohumoral factors should be regulated in the corresponding age groups to promote secretion of IGF and dopamine having an influence on the eye development and inhibit secretion of cortisol.

[0071] The control of each of the neurohumoral factors corresponds to the digital therapeutics module using environments (light), behaviors (exercise), emotions (reduced stress), and cognition (a sense of accomplishment) as imaginary parameters. Specific digital instructions for each module are generated based on the converted modules. In this case, the digital

instructions may include execution environment setups and modules (e.g., eye exercise, gymnastics, ego, safety/comfort, fun, and accomplishment modules), which may be output by monitoring. However, the modules are given by way of illustration only, and are not intended to be limiting to the
5 modules according to the present invention.

[0072] Meanwhile, referring to FIG. 5B, the background factors may be considered together in the design of the modules in the digital apparatus and the application for treating myopia according to one embodiment of the present invention.

10 **[0073]** In this case, the background factors are elements necessary for correction of clinical trial outcomes during verification of the clinical effectiveness of digital myopia therapy according to the present invention. Specifically, in the background factors shown in FIG. 5B, the basal factors may include activity, heart rates, sleep, meals (nutrition and calories), and the
15 like, the medical information may include EMR, family history, genetic vulnerability, and susceptibility, and the like, which have been written when a patient visited a hospital, and the digital therapeutics literacy may include the patient's accessibility to the digital therapy instructions and the apparatus, and an acceptance posture.

20 **[0074]** FIG. 6 is a diagram showing a method of assigning a patient-customized digital prescription using the digital apparatus and the application for treating myopia according to one embodiment of the present invention.

[0075] FIG. 6(A) show a prescription procedure for routine medical condition checkup of a patient by a doctor, and FIG. 6(B) show a method of
25 allowing a doctor to assign a patient-customized digital prescription based on

the analysis of a plurality of digital instructions and execution outcomes of the digital instructions.

[0076] In this way, when the digital apparatus and the application for treating myopia according to one embodiment of the present invention are used, the doctor may check the patient's instructions and execution outcomes for a given period and adjust the types of modules for treating myopia, and the instructions for each module in a patient-customized manner, as shown in FIG. 6(B).

[0077] FIG. 7A shows execution environment setups according to one embodiment of the present invention, and FIGS. 7B to 7G show examples of specific instructions for each module, and methods of collecting output data according to one embodiment of the present invention.

[0078] For digital therapy of axial myopia, because the patient's persistent participation is generally essential for 10 weeks or more, it is far more important that adolescent children have fun in digital therapy and voluntarily participate in the digital therapy. In this context, the modules may be configured by adding game elements to each module. In the digital apparatus and the application for treating myopia, which have been realized to relieve and treat axial myopia, as will be described below, each module is a basic design unit and is a collection of specific instructions.

[0079] Referring to FIG. 7A, specific examples of instructions for execution environment setups, and a method of collecting output data are shown. In this case, the execution environment setups may be included as part of the configuration of the digital instruction generation unit 010 shown in FIG. 2.

[0080] Specifically, the execution environment setups include setup of brightness of an execution environment using an illuminance sensor, and other modules are executed under a set light environment.

[0081] In general, sunlight is closely related to the eye health. The same
5 strong light stimulation as in exposure to direct sunlight acts in nerve cells of the retina to promote secretion of dopamine, thereby inducing synthesis of proteoglycans. This is a factor essential for normally adjusting an axial length of the eye.

[0082] As described above, the illuminance under a current environment
10 may be measured using an illuminance sensor to provide light stimuli to a patient, an alarm of a current light environment may be provided to brightly control an environment at which a patient participates in digital therapy.

[0083] Referring to FIG. 7B, specific examples of instructions for an eye exercise module, and a method of collecting output data are shown. In this
15 case, the may be included as part of the configuration of the digital instruction generation unit 010 shown in FIG. 2.

[0084] The digital instructions for eye exercise include controlling the patient's eye exercise, biofeedbacks, eyeball-related behaviors, and the like, and promote secretion of IGF in oculomotor muscles. Specifically,
20 behavioral instructions for the eye exercise module may monitor the patient's adherence using eye tracking technology such as eye exercise, eye blinking, remote staring, eye closing, and the like. However, a collection of the execution outcomes for the eye exercise module is not limited to the eye tracking technology, and include directly inputting the execution outcomes of
25 the instructions by the patient.

[0085] Referring to FIG. 7C, specific examples of instructions for a physical exercise module, and a method of collecting output data are shown. In this case, the physical exercise module may be included as part of the configuration of the digital instruction generation unit 010 shown in FIG. 2.

5 The physical exercise module includes slow and comfortable physical exercise, and abdominal exercise, and may be composed of a series of behavioral instructions configured to reduce stress through breaks, relaxation, deep breathing, and the like in order to inhibit secretion of cortisol.

[0086] Specifically, the behavioral instructions for the physical exercise
10 module include behavioral instructions such as relaxation exercise, deep breathing, meditation, eye massage, and the like. Also, the behavioral instructions include a method of collecting the execution outcomes of the behavioral instructions at the sensing data collection unit 020 using a biofeedback apparatus (for measuring EEG, ECG, EMG, EDG, etc.) or a
15 general-purpose sensor (for measuring activity, HR, etc.), or a method of allowing a patient to directly input the execution outcomes using the execution input unit 030. The behavioral instructions of the present invention are composed based on a behavior therapy method which is widely used to relieve stress of children in the child psychiatry.

20 **[0087]** In general, the progression of myopia is closely related to the course of adolescence. In particular, there might be a great deal of variation among the adolescent children in this stage, depending on the age, gender, character, and preference of the children. To cover these deviations, it is desirable that the digital instructions for each module are presented in a
25 customized manner according to the individual characteristics of each patient.

In particular, instructions requiring the mutual communication (for example, conversation) with an application may be developed in combination with big data analysis and artificial intelligence analysis.

[0088] Referring to FIG. 7D, specific examples of instructions for an ego module, and a method of collecting output data are shown. In this case, the ego module may be included as part of the configuration of the digital instruction generation unit 010 shown in FIG. 2.

[0089] Specifically, the instructions for the ego module aim to serve to increase the adolescents' self-esteem and relieve the stress. To do this, the instructions for the ego module may, for example, include instructions such as conversation, drawing, meditation, diary writing, making his/her own safe space (safety place instructions), his/her favorites (places, time, seasons, colors, foods, humans, etc.), his/her own bucket lists, choosing places to travel and planning for travel, and the like. These instructions are composed based on a psychotherapy which has been widely used in the child psychiatry to increase the self-esteem and relieve the stress of children or adolescents.

[0090] Referring to FIG. 7E, specific examples of instructions for a safety/comfort module, and a method of collecting output data are shown. In this case, the safety/comfort module may be included as part of the configuration of the digital instruction generation unit 010 shown in FIG. 2.

[0091] Specifically, the instructions for the safety/comfort module aim to serve as ventilation to reduce the adolescents' stress. To do this, the instructions for the safety/comfort module may, for example, include instructions such as chatting, expression (writing, singing, drawing), leaving

unpleasant emotions in an animational aspect (trash can instructions), and the like. These instructions are composed based on a psychotherapy which has been widely used in the child psychiatry to increase the self-esteem and relieve the stress of children or adolescents.

5 **[0092]** Referring to FIG. 7F, specific examples of instructions for a fun module, and a method of collecting output data are shown. In this case, the fun module may be included as part of the configuration of the digital instruction generation unit 010 shown in FIG. 2.

[0093] Specifically, the instructions for the fun module are instructions that
10 allow a patient to use an application and have fun, may be composed of various contents such as music, games, or videos, depending on the adolescent characteristics. Also, fun instructions in the fun module also aim to improve the patient's persistent participation in the digital therapy.

[0094] Referring to FIG. 7G, specific examples of instructions for an
15 accomplishment module, and a method of collecting output data are shown. In this case, the accomplishment module may be included as part of the configuration of the digital instruction generation unit 010 shown in FIG. 2.

[0095] Specifically, the instructions for the accomplishment module may include instructions that promote secretion of dopamine through senses of
20 accomplishment such as the patient's task execution and completion. Here, the task accomplishment instructions are instructions that allow a patient to feel a sense of accomplishment when a given task is accomplished, and thus may include games whose tasks may be updated over a patient's participation duration and which may induce the patient's voluntary
25 participation. For example, a specific format of the game may be composed

of various times such as learning, hidden or difference pictorial puzzles, quizzes, and the like.

[0096] In particular, some instructions realized in the form of quizzes at the accomplishment module may be expected to have an additional effect of
5 improving the patient's health information literacy and digital therapeutics literacy. Such improvement of the health information and digital therapeutics literacy is an element essential for the patient's persistent participation and execution in the therapy.

[0097] As mentioned above, the digital therapy according to the present
10 invention requires not less than 10 weeks of the patient's participation. During this period, sincerely executing the instructions for the aforementioned modules makes it possible to form compliment instructions in the accomplishment module so that a patient feels a sense of accomplishment. For the compliment instructions, the patient's active participation in the
15 therapy may be fed back as a sense of accomplishment based on the reliance and compensation between the patient and a guardian and between the patient and the doctor.

[0098] The digital instruction shown above in FIG. 7B to FIG. 7G are given by way of illustration only, and are not intended to limit the present invention.
20 For example, the digital instructions provided to the patient may be set in various manners, when necessary.

[0099] FIG. 8 is a flowchart illustrating operations in the digital application for treating myopia according to one embodiment of the present invention.

[00100] Referring to FIG. 8, the digital application for treating myopia
25 according to one embodiment of the present invention may first generate a

digital therapeutics module for treating myopia based on the mechanism of action in and the therapeutic hypothesis for myopia (S810). In this case, in S810, the digital therapeutics module may be generated based on the neurohumoral factors (for example, IGF, cortisol, dopamine, etc.) for myopia.

5 **[00101]** Meanwhile, in S810, the digital therapeutics module may be generated based on the inputs from the doctor. In this case, a digital therapeutics module may be generated based on the information collected by the doctor when diagnosing a patient, and the prescription outcomes recorded based on the information. Also, in S810, the digital therapeutics
10 module may be generated based on the information (for example, basal factors, medical information, digital therapeutics literacy, etc.) received from the patient.

[00102] Next, in S820, specified digital instructions may be generated based on the digital therapeutics module. S820 may generate a digital
15 therapeutics module by applying imaginary parameters about the patient's environments, behaviors, emotions, and cognition to the mechanism of action in and the therapeutic hypothesis for myopia. This digital therapeutics module is described with reference to FIG. 5, and thus description thereof will be omitted.

20 **[00103]** In this case, the digital instructions may be generated for at least one of light environment setup, eye exercise, physical exercise, ego, safety/comfort, fun, and accomplishment modules. Description of the execution environment setups and the specific digital instructions for each of the modules is as described in FIGS. 7A to 7G.

[00104] Then, the digital instructions may be provided to a patient (S830).

In this case, the digital instructions may be provided in the form of digital instructions which are associated with behaviors, emotions, cognition and in which the patient's instruction adherence such as eye exercise/physical exercise may be monitored using a sensor, or provided in the form of digital instructions in which a patient is allowed to directly input the execution outcomes.

[00105] After the patient executes the presented digital instructions, the patient's execution outcomes of the digital instructions may be collected

10 (S840). In S840, the execution outcomes of the digital instructions may be collected by monitoring the patient's adherence to the digital instructions as described above, or allowing the patient to input the execution outcomes of the digital instructions.

[00106] Meanwhile, the digital application for treating myopia according to

15 one embodiment of the present invention may repeatedly execute operations several times, wherein the operations include generating the digital instruction and collecting the patient's execution outcomes of the digital instructions. In this case, the generating of the digital instruction may include generating the patient's digital instructions for this cycle based on the patient's digital instructions provided in the previous cycle and the execution outcome data on the patient's collected digital instructions provided in the previous cycle.

[00107] As described above, according to the digital application for treating myopia according to one embodiment of the present invention, the reliability

25 of the inhibition of progression of and treatment of myopia may be ensured

by deducing the mechanism of action in and the therapeutic hypothesis for myopia in consideration of the neurohumoral factors for myopia, presenting the digital instructions to a patient based on the mechanism of action in and the therapeutic hypothesis for myopia, executing the digital instructions under
5 a suitable light stimulus environment, and collecting and analyzing the outcomes of the digital instructions.

[00108] Although the digital apparatus and the application for treating myopia according to one embodiment of the present invention have been described in terms of myopia therapy, the present invention is not limited
10 thereto. For the other diseases other than the myopia, the digital therapy may be executed substantially in the same manner as described above.

[00109] FIG. 9 is a flowchart illustrating a method of generating digital instructions in the digital application for treating myopia according to one embodiment of the present invention.

15 **[00110]** Referring to FIG. 9, operations of the method of generating digital instructions are as described above in the process of generating the module for treating myopia and the specified digital instructions based on the mechanism of action in and the therapeutic hypothesis for myopia (S810 and S820 shown in FIG. 8) and the processes shown in FIG. 5.

20 **[00111]** In S910, first of all, the mechanism of action in and the therapeutic hypothesis for myopia may be input. In this case, the mechanism of action in and the therapeutic hypothesis for myopia may be previously deduced through the literature search and expert reviews on the systematic related clinical trials on myopia, as described above.

[00112] Next, neurohumoral factors for myopia may be predicted from the input mechanism of action and therapeutic hypothesis (S920). In this case, the neurohumoral factors for myopia predicted in S920 may be deduced in the form of IGF, cortisol, dopamine, and the like. These neurohumoral factors have been described in detail with reference to FIG. 5, and thus description thereof will be omitted.

[00113] In S930, a digital therapeutics module may be generated so that the imaginary parameters can correspond to the predicted neurohumoral factors. Here, the imaginary parameters may serve as converters that convert the neurohumoral factors for myopia into a digital therapeutics module, and this procedure is to set the physiological interrelation between the neurohumoral factors and the environmental, behavioral, emotional and cognition factors, as shown in FIG. 5.

[00114] Then, specified digital instructions may be generated based on the generated digital therapeutics module (S940). In this case, the specific digital instructions may be generated at the aforementioned light environment setup, eye exercise, physical exercise, ego, safety/comfort, fun, and accomplishment modules with reference to FIGS. 7A to 7G.

[00115] FIG. 10 is a flowchart illustrating a method of repeatedly executing the operations under the feedback control in the digital application for treating myopia according to one embodiment of the present invention.

[00116] In FIG. 10, it is explained that generation of the digital instructions and collection of the execution outcomes at the digital application for treating myopia are executed N times. In this case, the mechanism of action in and the therapeutic hypothesis for myopia may be first input (S1010). Also, the

digital instructions provided in the previous cycle, and the execution outcome data may be received (S1020). When the first cycle of execution is now in progress, S1020 may be omitted because there are no previous data.

[00117] Next, digital instructions for this cycle may be generated based on
5 the input mechanism of action and therapeutic hypothesis, the digital instruction provided in the previous cycle, and the execution outcome data (S1030). Then, the user's execution outcomes of the generated digital instructions may be collected (S1040).

[00118] In S1050, it is judged whether this cycle is greater than N^{th} cycle.
10 When this cycle is less than the N^{th} cycle (NO), this may return again to S1020, thus repeatedly executing S1020 to S1040. On the other hand, when this cycle is greater than the N^{th} cycle (YES), that is, when the generation of the digital instructions and the collection of the execution outcomes are executed N times, a feedback operation may be terminated.

15 **[00119]** FIG. 11 is a diagram showing a hardware configuration of the digital apparatus for treating myopia according to one embodiment of the present invention.

[00120] Referring to FIG. 11, hardware 600 of the digital apparatus for treating myopia according to one embodiment of the present invention may
20 include a CPU 610, a memory 620, an input/output I/F 630, and a communication I/F 640.

[00121] The CPU 610 may be a processor configured to execute a digital program for treating myopia stored in the memory 620, process various data for treating digital myopia and execute functions associated with the digital
25 myopia therapy. That is, the CPU 610 may act to execute functions for each

of the configurations shown in FIG. 2 by executing the digital program for treating myopia stored in the memory 620.

[00122] The memory 620 may have a digital program for treating myopia stored therein. Also, the memory 620 may include the data used for the digital myopia therapy included in the aforementioned database 050, for example, the patient's digital instructions and instruction execution outcomes, the patient's medical information, and the like.

[00123] A plurality of such memories 620 may be provided, when necessary. The memory 620 may be a volatile memory or a non-volatile memory. When the memory 620 is a volatile memory, RAM, DRAM, SRAM, and the like may be used as the memory 620. When the memory 620 is a non-volatile memory, ROM, PROM, EAROM, EPROM, EEPROM, a flash memory, and the like may be used as the memory 620. Examples of the memories 620 as listed above are given by way of illustration only, and are not intended to limit the present invention.

[00124] The input/output I/F 630 may provide an interface in which input apparatuses (not shown) such as a keyboard, a mouse, a touch panel, and the like, and output apparatuses such as a display (not shown), and the like may be connected to the CPU 610 to transmit and receive data.

[00125] The communication I/F 640 is configured to transmit and receive various types of data to/from a server, and may be one of various apparatuses capable of supporting wire or wireless communication. For example, the types of data on the aforementioned digital behavior-based therapy may be received from a separately available external server through the communication I/F 640.

[00126] As described above, the computer program according to one embodiment of the present invention may be recorded in the memory 620 and processed at the CPU 610, for example, so that the computer program can be realized as a module configured to execute each of functional blocks
5 shown in FIG. 2.

[00127] It will be understood that when an element is referred to as being “connected” or “coupled” to another element, it can be directly connected or coupled to the other element or intervening elements may be present. In contrast, when an element is referred to as being “directly connected” or
10 “directly coupled” to another element, there are no intervening elements present.

[00128] It will be further understood that the terms “comprises,” “comprising,” “includes” and/or “including,” when used herein, specify the presence of stated features, integers, steps, operations, elements,
15 components and/or groups thereof, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components and/or groups thereof.

[00129] While the invention has been shown and described with reference to certain exemplary embodiments thereof, it will be understood by those skilled
20 in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

WHAT IS CLAIMED IS:

1. A digital apparatus for treating myopia, comprising:
 - a digital instruction generation unit configured to generate digital
5 therapeutic modules for treating myopia based on a mechanism of action
(MOA) in and a therapeutic hypothesis for the myopia, generate specified
digital instructions based on the digital therapeutic modules, and provide the
digital instructions to a first user; and
an outcome collection unit configured to collect the first user's
10 execution outcomes of the digital instructions.
2. The digital apparatus of claim 1, wherein the digital instruction
generation unit generates the digital therapeutic modules based on
neurohumoral factors related to the myopia onset.
15
3. The digital apparatus of claim 2, wherein the neurohumoral factors
comprise insulin-like growth factor (IGF), cortisol, and dopamine.
4. The digital apparatus of claim 1, wherein the digital instruction
20 generation unit generates the digital therapeutic modules based on the inputs
from a second user.

5. The digital apparatus of claim 1, wherein the digital instruction generation unit generates the digital therapeutic modules based on the information received from the first user.

5 6. The digital apparatus of claim 5, wherein the information is received from the first user comprises at least one of basal factors, medical information, and digital therapeutics literacy of the first user,

 the basal factors including the first user's activity, heart rate, sleep, and diet (including nutrition and calories),

10 the medical information including the first user's electronic medical record (EMR), family history, genetic vulnerability, and genetic susceptibility, and

 the digital therapeutics literacy including the first user's accessibility, and technology adoption to the digital therapeutics and the apparatus.

15

 7. The digital apparatus of claim 1, wherein the digital instruction generation unit generates the digital therapeutic modules matching to imaginary parameters which correspond to the mechanism of action in and the therapeutic hypothesis for the myopia.

20

 8. The digital apparatus of claim 7, wherein the imaginary parameters are deduced in relation to the first user's environment, behaviors, emotions, and cognition.

9. The digital apparatus of claim 1, wherein the digital instruction generation unit generates the digital therapeutic modules and corresponding digital instructions, responding to at least one of light environment, exercise, reduced stress, and accomplishment.

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10. The digital apparatus of claim 9, wherein the digital instructions for the light environment comprise controlling the first user's light environment.

11. The digital apparatus of claim 9, wherein the digital instructions for
10 the exercise comprise at least one of patients' eyeball exercise, biofeedback, eyeball-related behavior control by the first user.

12. The digital apparatus of claim 9, wherein the digital instructions for
the reduced stress comprise at least one of the first user's instructions for
15 physical exercise, ego, safety/comfort, fun modules.

13. The digital apparatus of claim 9, wherein the digital instructions for
the accomplishment comprise instructions regarding task accomplishment
and instructions for providing compensation for the digital instruction
20 executions to the first user.

14. The digital apparatus of claim 1, wherein the outcome collection
unit collects the execution outcomes of the digital instructions by monitoring
the first user's adherence to the digital instructions or allowing the first user to
25 directly input the first user's adherence to the digital instructions.

15. The digital apparatus of claim 1, wherein the generation of the digital instructions at the digital instruction generation unit and the collection of the first user's execution outcomes of the digital instructions at the outcome collection unit are repeatedly executed several times with multiple feedback loops, and

the digital instruction generation unit generates the first user's digital instructions for this cycle based on the first user's digital instructions in the previous cycle and the execution outcome data on the first user's digital instructions in the previous cycle collected at the outcome collection unit.

16. A digital application for treating myopia that instructs a computing apparatus to execute operations, comprises:

generating digital therapeutic modules for treating myopia based on a mechanism of action in and a therapeutic hypothesis for the myopia;

generating specified digital instructions based on the digital therapeutic modules;

providing the digital instruction to a first user; and

collecting the first user's execution outcomes of the digital instructions.

20

17. The digital application of claim 16, wherein the generating of the digital therapeutic modules comprises generating the digital therapeutic modules based on neurohumoral factors related to the myopia onset.

18. The digital application of claim 16, wherein the generating of the digital therapeutic modules comprises generating the digital therapeutic modules by applying imaginary parameters about the first user's environments, behaviors, emotions, and cognition to the mechanism of action
5 in and the therapeutic hypothesis for the myopia.

19. The digital application of claim 16, wherein the generating of the digital instructions comprises generating digital instructions for at least one of light environment, exercise, reduced stress, and accomplishment.
10

20. The digital application of claim 16, wherein the generating of the digital instructions and the collecting of the first user's execution outcomes of the digital instructions are repeatedly executed several with multiple feedback loops, and
15 the generating of the digital instructions comprises generating the first user's digital instructions for this cycle based on the first user's digital instructions in the previous cycle and the collected execution outcome data on the first user's digital instructions provided in the previous cycle.

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