developmental delays, non-verbal developmental delays, intellectual disabilities, intellectual disabilities of known or unknown genetic origin, traumatic brain injuries, disorders of infancy not otherwise specified (DOI-NOS), social communication disorder, and autism spectrum disorders (ASD), as well as such conditions as attention deficit hyperactivity disorder (ADHD), attention deficit disorder (ADD), post-traumatic stress disorder (PTSD), concussion, sports injuries, and dementia. The present systems, devices, and methods are also applicable to the measurement of developmental, cognitive, social, or mental abilities such as, but not limited to, expressive and receptive language levels in the normative to exceptional range, non-verbal cognitive function in the normative to exceptional range, and social developmental levels in the normative to exceptional range. Furthermore, such systems, devices, and methods can be applied to quantitatively measure and monitor symptomatology of the respective ability or disability and, in certain cases, provide more accurate and relevant prescriptive information to patients, families, and service providers. According to the present disclosure, the disclosed systems, device, and methods can be used to predict outcome in subjects with autism (thus providing prescriptive power) while also providing similar diagnostic and prescriptive measures for global developmental, cognitive, social, or mental ability or disabilities.

According to some embodiments, the present systems, devices, and methods relate to assessing the risk of developmental, cognitive, social, or mental abilities or disabilities in very young patients (e.g., in the first 2-6 months of life). According to the present disclosure, the decline in visual fixation of a subject over time with respect to certain dynamic stimuli provides a marker of a possible developmental, cognitive, social, or mental abilities or disabilities (such as ASD) of the subject. The visual fixation of the subject is identified, monitored, and tracked over time (e.g., in the first 6 months of life) through repeated eye tracking sessions, and data relating to the visual fixation is then compared to relative norms to determine a possible increased risk of such a condition in the subject. A change in visual fixation (in particular, a decline in visual fixation by a subject with the image of eyes, body, or other region-of-interest of a person or object displayed on a visual stimulus) as compared to similar visual fixation data of typically-

the individual, receiving eye movement data from the eye tracking device that indicates visual fixation of the individual with respect to a particular spatial region-of-interest associated with the eyes of the actor portraying the caregiver in the displayed visual stimulus; (e) repeating steps a-d for a plurality of sessions within the first 24 months of life of the individual, wherein each session is separated by at least about one month; (f) upon completion of steps a-e, generating, via software executing on a processor, a representation of the received eye movement data over the plurality of sessions, wherein the representation demonstrates a change or rate-of-change in visual fixation for the individual over the plurality of sessions; (g) retrieving, via software executing on the processor, a comparison representation of change or rate-of-change in visual fixation for a comparison group with respect to a comparable plurality of sessions; and (h) comparing, via software executing on the processor, the change or rate-of-change in visual fixation for the individual to the change or rate-of-change in visual fixation for the comparison group to determine whether the change or rate-of-change in visual fixation for the individual falls outside a predetermined range of the change or rate-of-change in visual fixation for the comparison group and thereby indicates a likelihood that the individual has a developmental, cognitive, social, or mental disorder.

In one aspect of the present disclosure, there is provided a method for evaluating, monitoring or diagnosing a developmental, cognitive, social, or mental disability or ability based on identifying a change in visual fixation of an individual over time during at least two sessions, comprising the steps of:

providing a data collection apparatus, the apparatus having a display device for displaying a stimulus to an individual and a sensor for detecting visual fixation of the individual in response to the stimulus displayed by the display device, wherein the sensor allows for collection of eye movement data;

receiving first eye movement data obtained from the sensor that indicates visual fixation of the individual with respect to a displayed first visual stimulus;

receiving second eye movement data obtained from the sensor that indicates visual fixation of the individual with respect to a displayed second visual stimulus, wherein the second eye movement data was obtained during a second session performed after a first session in which the first eye movement data was collected; and

comparing, via software executing on a processor, the first eye movement data to the second eye movement data to identify a change in visual fixation for the individual with respect to the displayed first visual stimulus and the displayed second visual stimulus,

wherein the change in visual fixation over time for the individual is a marker of a developmental, cognitive, social, or mental disability or ability.

In another aspect of the present disclosure, there is provided a method for identifying a change in visual fixation of an individual over time, comprising the steps of:

receiving a first data set collected from an eye tracking device indicative of an individual's visual fixation with respect to a first visual stimulus, wherein the individual's visual fixation corresponds to at least one spatial region-of-interest in the first visual stimulus;

receiving a second data set collected from the eye tracking device indicative of the individual's visual fixation with respect to a second visual stimulus, wherein the individual's visual fixation corresponds to at least one spatial region-of-interest in the second visual stimulus, and wherein the second data set was collected during a second session performed after a first session in which the first data set was collected;

generating, via software executing on a processor, a representation of the first data set and the second data set, wherein the representation demonstrates visual fixation with respect to the at least one spatial region-of-interest; and

calculating, via software executing on a processor, a rate-of-change in visual fixation for the individual from the first session to the second session based on the representation of the first data set and the second data set,

wherein the rate-of-change in visual fixation from the first session to the second session for the individual is a marker of a developmental, cognitive, social, or mental disability or ability.

In a further aspect of the present disclosure, there is provided a method for evaluating, monitoring or diagnosing a developmental, cognitive, social, or mental disability or ability based on rate-of-change of visual fixation of an individual over time during at least two sessions, comprising the steps of:

providing a data collection apparatus, the apparatus having a display device for displaying a stimulus to an individual and a sensor for detecting visual fixation of the individual in response to the stimulus displayed by the display device, wherein the sensor allows for collection of eye movement data;

receiving first eye movement data obtained from the sensor that indicates visual fixation of the individual with respect to a displayed first visual stimulus;

receiving second eye movement data obtained from the sensor that indicates visual fixation of the individual with respect to a displayed second visual stimulus, wherein the second eye movement data was obtained during a second session performed after a first session in which the first eye movement data was collected;

generating, via software executing on a processor, a representation of the first eye movement data and the second eye movement data, wherein the representation demonstrates a rate-of-change in visual fixation for the individual from the first session to the second session;

retrieving, via software executing on the processor, a comparison representation of rate-of-change in visual fixation for a comparison group with respect to the displayed first visual stimulus and the displayed second visual stimulus; and

comparing, via software executing on the processor, the rate-of-change in visual fixation for the individual to the rate-of-change in visual fixation for the comparison group to determine whether the rate-of-change in visual fixation for the individual falls outside a predetermined range of the rate-of-change in visual fixation for the comparison group and thereby indicates a likelihood that the individual has a developmental, cognitive, or mental disability or ability.

According to the present disclosure, the change in visual fixation of an individual comprises a decline in visual fixation of the individual with respect to the displayed first visual stimulus as compared to the displayed second visual stimulus. Also according to the present disclosure, the change in visual fixation of the individual with respect to the displayed first visual stimulus as compared to the displayed second visual stimulus comprises a change in visual fixation that is statistically different from a change in visual fixation measured in a comparison group of individuals. According to certain embodiments, the change in visual fixation comprises a deviation in visual fixation equal to or greater than 1.96 times the standard error of the mean change in visual fixation of a comparison group.

According to the present disclosure, the first eye movement data and the second eye movement data include visual fixation data indicative of the individual's visual fixation with respect to one or more regions-of-interest in the displayed first visual stimulus and

the displayed second visual stimulus. Also according to the present disclosure, the one or more regions-of-interest are spatially predefined. Additionally, according to the present disclosure, the one or more regions-of-interest comprise one or more discrete regions of visual space. Also according to the present disclosure , the one or more discrete regions of visual space are measured in degrees of visual angle equal to at least twice the minimum resolvable accuracy of the first eye movement data or the second eye movement data with 95% statistical confidence.

According to the present disclosure, the step of comparing the first eye movement data to the second eye movement data further comprises generating, via software executing on the processor, a graphical representation of the individual's visual fixation with respect to the one or more regions-of-interest in the displayed first visual stimulus and the displayed second visual stimulus. Also according to the present disclosure, the graphical representation of the individual's visual fixation comprises one or more graduated lines marking measures of variance with respect to a comparison group. Additionally, according to the present disclosure, the graduated lines marking measures of variance may comprise percentiles, standard deviations, or some other measure. Also according to the present disclosure, the change in visual fixation comprises a decline in spatial visual fixation of the individual with respect to the one or more regions-of-interest.

According to the present disclosure, the visual stimulus (e.g., first visual stimulus and/or the second visual stimulus) comprise one or more of a static visual stimulus, a dynamic visual stimulus, a pre-recorded visual stimulus, a pre-recorded audiovisual stimulus, a live visual stimulus, a live audiovisual stimulus, a two-dimensional stimulus, or a three- dimensional stimulus. Also according to the present disclosure, the visual stimuli are normed for eliciting specific eye movement responses with greater than 95% statistical confidence. Additionally, according to the present disclosure, the visual stimuli elicit eye movement responses to discrete spatial-temporal locations with greater than 95% statistical confidence. Also according to the present disclosure, the visual stimuli have measurable presentation durations equal to at least half the minimum eye movement fixation duration for the individual. Additionally, according to the present disclosure, the minimum eye movement fixation may be measured, for example, in milliseconds or some other relevant time measure. Also according to the present disclosure, the first visual stimulus is the same as the second visual stimulus. Additionally, according to the present disclosure, the first visual stimulus is different from the second visual stimulus.

According to the present disclosure, the data collection apparatus is specifically adapted for individuals less than 24 months old. Also according to the present disclosure, the data collection apparatus is specifically adapted for individuals less than 6 months old. Additionally, according to the present disclosure, the data collection apparatus includes a support device for seating and confining the individual in the orientation with respect to the display device and the sensor. Also according to the present disclosure, the data collection apparatus includes a support device for linearly positioning the individual with respect to the display device such that a linear distance from the display device to the individual's eyes is minimized, while the available dynamic focal range of the eye movement sensor is maximized. Additionally, according to the present disclosure, the linear distance is in a range of about 40-80 cm and wherein the available dynamic focal range is about 50-70 cm.

According to the present disclosure, the data collection apparatus includes a support device for rotationally positioning the individual's head and eyes in a rotational position with respect to the display device such that eyelid separation, when not blinking, is maximized at the widest physical distance, while occlusion of the cornea by the eyelid is minimized or eliminated. Also according to the present disclosure, the rotational position of the head of the individual with respect to the display device is tilted forwards and downwards in a range of about 0-24 degrees. Additionally, according to the present disclosure, the sensor comprises an eye tracking device. Also according to the present disclosure, the steps of positioning the individual in the data collection apparatus further comprise positioning the individual's eyes are about 60 cm from the display device and the sensor, positioning the head of the individual at an angle tilted forwards and downwards at about 12 degrees, and stabilizing head and neck supports of the data collection apparatus to maintain the position.

According to the present disclosure, when at least two sessions are conducted, the first session and the second session occur at two of the following ages of an individual: 2 months old, 3 months old, 4 months old, 5 months old, 6 months old, 9 months old, 12 months old, 15 months old, 18 months old, and 24 months old. Also according to the present disclosure, the first session and second session are separated by a predetermined time period, which may be at least one calendar month.

According to the present disclosure, the step of scrubbing the eye movement data to remove poor quality data points based on insufficient data collection and/or poor quality data. Also according to the present disclosure, an interpretation of insufficient data collection may be comprised of one or more of the following: a static threshold for setting the minimum percentage of visual fixation directed towards the stimulus, a fuzzy logic or adaptive threshold for setting the minimum percentage of visual fixation directed towards the stimulus, a static threshold for setting the minimum percentage of visual fixation directed away from the stimulus, a fuzzy logic or adaptive threshold for setting the minimum percentage of visual fixation directed away from the stimulus. Additionally according to the present disclosure, an interpretation of poor quality data may be comprised of one or more of the following: a static threshold for poor quality calibration accuracy, a fuzzy logic or adaptive threshold for poor quality calibration accuracy, a static threshold for low signalto- noise ratio during fixation eye movements, a fuzzy logic or adaptive threshold for low signal-to-noise ratio during fixation eye movements, a static threshold for ratio of head movement artifact to eye movement signal, a fuzzy logic or adaptive threshold for ratio of head movement artifact to eye movement signal. Also according to the present disclosure, one interpretation of signal-to-noise ratio during fixation eye movements may be quantified as the measurement variance in fixation location relative to the measurement mean fixation location, in one or more eye movement fixations.

Variations and modifications of these embodiments and aspects will occur to those of skill in the art after reviewing this disclosure. The foregoing features and aspects may be implemented, in any combination and subcombination (including multiple dependent combinations and subcombinations), with one or more other features described herein. The various features described or illustrated herein, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented.

CLAIMS

What is claimed is:

1. A method for evaluating, monitoring or diagnosing a developmental, cognitive, social, or mental disability or ability based on identifying a change in visual fixation of an individual over time during at least two sessions, comprising the steps of:

providing a data collection apparatus, the apparatus having a display device for displaying a stimulus to an individual and a sensor for detecting visual fixation of the individual in response to the stimulus displayed by the display device, wherein the sensor allows for collection of eye movement data;

receiving first eye movement data obtained from the sensor that indicates visual fixation of the individual with respect to a displayed first visual stimulus;

receiving second eye movement data obtained from the sensor that indicates visual fixation of the individual with respect to a displayed second visual stimulus, wherein the second eye movement data was obtained during a second session performed after a first session in which the first eye movement data was collected; and

comparing, via software executing on a processor, the first eye movement data to the second eye movement data to identify a change in visual fixation for the individual with respect to the displayed first visual stimulus and the displayed second visual stimulus,

wherein the change in visual fixation over time for the individual is a marker of a developmental, cognitive, social, or mental disability or ability.

14. The method of any of claims 1-13, wherein the first visual stimulus and/or the second visual stimulus have measurable presentation durations equal to at least half the minimum eye movement fixation duration for the individual.

15. The method of any of claims 1-14, wherein the first visual stimulus is the same as the second visual stimulus.

16. The method of any of claims 1-13, wherein the first visual stimulus is different from the second visual stimulus.

17. The method of any of claims 1-15, wherein the data collection apparatus is specifically adapted for individuals less than 24 months old.

18. The method of any of claims 1-16, wherein the data collection apparatus is specifically adapted for individuals less than 6 months old.

19. The method of any of claims 1-17, wherein the first session and the second session occurred at two of the following ages of the individual: 2 months old, 3 months old, 4 months old, 5 months old, 6 months old, 9 months old, 12 months old, 15 months old, 18 months old, and 24 months old.

20. The method of any of claims 1-19, wherein the data collection apparatus includes a support device for seating and confining the individual in the orientation with respect to the display device and the sensor.

21. The method of any of claims 1-20, wherein the data collection apparatus includes a support device for linearly positioning the individual with respect to the display device such that a linear distance from the display device to the individual's eyes is minimized, while the available dynamic focal range of the eye movement sensor is maximized.

22. The method of claim 21, wherein the linear distance is in a range of about 40-80 cm and wherein the available dynamic focal range is about 50-70 cm.

23. The method of any of claims 1-22, wherein the data collection apparatus includes a support device for rotationally positioning the individual's head and eyes in a rotational position with respect to the display device such that eyelid separation, when not blinking, is maximized at the widest physical distance, while occlusion of the cornea by the eyelid is minimized or eliminated.

24. The method of claim 23, wherein the support device is for rotationally positioning the head of the individual with respect to the display device at an angle tilted forwards and downwards in a range of about 0-24 degrees.

25. The method of any of claim 1-24, wherein the sensor comprises an eye tracking device.

26. The method of any of claims 1-25, wherein the data collection apparatus includes a support device for positioning the individual's eyes about 60 cm from the display device and the sensor, positioning the head of the individual at an angle tilted forwards and downwards at about 12 degrees, and stabilizing head and neck supports of the data collection apparatus to maintain the position.

39. The method of any of claims 30-38, wherein the first visual stimulus and/or the second visual stimulus are normed for eliciting specific eye movement responses with greater than 95% statistical confidence.

40. The method of any of claims 30-38, wherein the first visual stimulus and/or the second visual stimulus elicit eye movement responses to discrete spatial-temporal locations with greater than 95% statistical confidence.

41. The method of any of claims 30-40, wherein the first visual stimulus and/or the second visual stimulus have measurable presentation durations equal to at least half the minimum eye movement fixation duration for the individual.

42. The method of any of claims 30-41, wherein the first visual stimulus is the same as the second visual stimulus.

43. The method of any of claims 30-41, wherein the first visual stimulus is different from the second visual stimulus.

44. The method of any of claims 30-43, wherein the first data set and the second data set are collected via a data collection apparatus.

45. The method of claim 44 wherein the data collection apparatus is specifically adapted for individuals less than 24 months old.

46. The method of claim 44, wherein the data collection apparatus is specifically adapted for individuals less than 6 months old.

47. The method of any of claim 44-46, wherein the data collection apparatus includes a support device for seating and confining the individual in a predetermined orientation with respect to the eye tracking device and a display device for displaying the first visual stimulus and the second visual stimulus.

48. The method of any of claims 44-47, wherein the data collection apparatus includes a support device for linearly positioning the individual with respect to the display device such that a linear distance from the display device to the individual's eyes is minimized, while the available dynamic focal range of the eye tracking device is maximized.

49. The method of claim 48, wherein the linear distance is in a range of about 40-80 cm and wherein the available dynamic focal range is about 50-70 cm.

50. The method of any of claims 44-49, wherein the data collection apparatus includes a support device for rotationally positioning the individual's head and eyes in a rotational position with respect to the display device such that eyelid separation, when not blinking, is maximized at the widest physical distance, while occlusion of the cornea by the eyelid is minimized or eliminated.

51. The method of claim 50, wherein the support device is for rotationally positioning the head of the individual with respect to the display device at an angle tilted forwards and downwards in a range of about 0-24 degrees.

52. The method of any of claims 47-57, wherein the predetermined orientation comprises a position of the individual such that the individual's eyes are about 60 cm from the display device and the eye tracking device, the head of the individual is tilted at an angle forwards and downwards at about 12 degrees, and the position is maintained by head and neck supports.

53. The method of any of claims 30-52, wherein the first session and the second session occurred at two of the following ages of the individual: 2 months old, 3 months old, 4 months old, 5 months old, 6 months old, 9 months old, 12 months old, 15 months old, 18 months old, and 24 months old.

54. The method of any of claims 30-53, wherein the first session and second session are separated by a predetermined time period.

55. The method of claim 54, wherein the predetermined time period is at least one calendar month.

56. The method of any of claims 30-55, further comprising the step of scrubbing the first data set and/or the second data set to remove poor quality data points based on insufficient data collection and/or poor quality data calibration.

57. A method for evaluating, monitoring or diagnosing a developmental, cognitive, social, or mental disability or ability based on rate-of-change of visual fixation of an individual over time during at least two sessions, comprising the steps of:

providing a data collection apparatus, the apparatus having a display device for displaying a stimulus to an individual and a sensor for detecting visual fixation of the individual in response to the stimulus displayed by the display device, wherein the sensor allows for collection of eye movement data;

receiving first eye movement data obtained from the sensor that indicates visual fixation of the individual with respect to a displayed first visual stimulus;

receiving second eye movement data obtained from the sensor that indicates visual fixation of the individual with respect to a displayed second visual stimulus, wherein the second eye movement data was obtained during a second session performed after a first session in which the first eye movement data was collected;

generating, via software executing on a processor, a representation of the first eye movement data and the second eye movement data, wherein the representation demonstrates a rate-of-change in visual fixation for the individual from the first session to the second session;

retrieving, via software executing on the processor, a comparison representation of rate-of-change in visual fixation for a comparison group with respect to the displayed first visual stimulus and the displayed second visual stimulus; and

comparing, via software executing on the processor, the rate-of-change in visual fixation for the individual to the rate-of-change in visual fixation for the comparison group to determine whether the rate-of-change in visual fixation for the individual falls

4 months old, 5 months old, 6 months old, 9 months old, 12 months old, 15 months old, 18 months old, and 24 months old.

77. The method of any of claims 57-76, wherein the data collection apparatus includes a support device for seating and confining the individual in the orientation with respect to the display device and the sensor.

78. The method of any of claims 57-77, wherein the data collection apparatus includes a support device for linearly positioning the individual with respect to the display device such that a linear distance from the display device to the individual's eyes is minimized, while the available dynamic focal range of the eye movement sensor is maximized.

79. The method of claim 78, wherein the linear distance is in a range of about 40-80 cm and wherein the available dynamic focal range is about 50-70 cm.

80. The method of any of claims 57-79, wherein the data collection apparatus includes a support device for rotationally positioning the individual's head and eyes in a rotational position with respect to the display device such that eyelid separation, when not blinking, is maximized at the widest physical distance, while occlusion of the cornea by the eyelid is minimized or eliminated.

81. The method of claim 80, wherein the support device is for rotationally positioning the head at an angle tilted forwards and downwards in a range of about 0-24 degrees.

82. The method of any of claims 57-81, wherein the sensor comprises an eye tracking device.

83. The method of any of claims 57-82, wherein the data collection apparatus includes a support device for positioning an individual's eyes about 60 cm from the display device and sensor, positioning the head of the individual at an angle tilted forwards and downwards 12 degrees, and stabilizing head and neck supports of the data collection apparatus to maintain the position.

84. The method of any of claims 57-83, wherein the first session and second session are separated by a predetermined time period.

85. The method of claim 84, wherein the predetermined time period is at least one calendar month.

86. The method of any of claims 57-85, further comprising the step of scrubbing the first eye movement data and/or second eye movement data to remove poor quality data points based on insufficient data collection and/or poor quality data calibration.