**Title:** BiAffect: a ResearchKit study to unobtrusively understand mood and cognition in bipolar disorder

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*Informed Consent Process*

Study participants self-enroll in the study electronically. This strategy is used such that BiAffect allows participants across the country to participate of their own accord, as in many of the public ResearchKit studies. In this case, the app provides only one piece of identifying information (email address) to the server. This information is sufficient to create an electronic record of consent to participate in a mobile study. This strategy has the broadest possible enrollment, and allows for study designs in which participants never physically interact with the study team.

Initial eligibility will be checked in the mobile application, and recorded as part of the study participant record through Bridge Server operated by Sage Bionetworks.

*Description of Procedures*

Total time required for subjects to be screened for eligibility and, if eligible, be subsequently consented will last up to 10 minutes. After enrollment, the overall duration of study participation will be expected to last 10 weeks.

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Self e-Consent/Eligibility Screening (10 minutes)

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Consent (time may vary)

During the TestFlight phase, anyone who signed up on the Mood Challenge for ResearchKit website will have a chance to download and beta-test the app, as long as they are adults (age >18) and use English as their primary language on iPhone.

However, screening for eligibility will include self-ratings of the Mood Disorder Questionnaire and a self-report of whether a prior bipolar disorder diagnosis is given.

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Keyboard installation

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After enrollment, the app will ask the participant to install the custom keyboard as a third-party keyboard extension. This process will occur instantaneously.

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Mood Survey Questionnaires and Active Tasks

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The participant will be notified by the app to complete brief daily mood surveys (~ 1 minute) as well as weekly mood surveys and active tasks (taking up to 5 minutes each time).

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Uninstallation

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At the end of the study, participants will be able to uninstall the keyboard application on their own by simply deleting the BiAffect iOS App. This process should take no more than 1-2 minutes.

*Brief descriptions of surveys employed by BiAffect:*

During enrollment:

1. Users will be asked if they have been previously given a diagnosis of bipolar disorder (any type) or not.

2. Users will be prompted to complete a self-administered Mood Disorder Questionnaire (1; Appendix A), commonly used as a screening tool for bipolar affective disorder, and is publicly available and can be retrieved from <http://www.sadag.org/images/pdf/mdq.pdf>

Daily:

Everyday the users will be prompted, using a slider, to quickly rate the following on a scale of 1-10:

1. Mood

2. Impulsiveness

3. Energy level

4. Speed of thoughts

Weekly:

1. The 9-item Patient Health Questionnaire or PHQ-9 (2; Appendix B) is a multiple-choice self-report commonly used as a screening and self-rating tool for depressive symptoms in a primary care setting.

2. The Altman Self-Rating Mania Scale (3; Appendix C) is a 5-item scale that allows for self- assessment of the presence and severity of manic/hypomanic symptoms in bipolar disorder.

*Brief descriptions of weekly active tasks employed by BiAffect:*

1. The *Spatial Memory task* is currently implemented as part of the standard active tasks in the ResearchKit framework. In short, a series of “flowers” are presented as a sequence on a grid, and the user is tasked to remember the positions and the correct order presented by tapping the same sequence right after it is presented.

2. The *Go-No-Go Reaction Time task* is a modified version of the existing ResearchKit reaction time task. In brief, the user will be presented with either a blue circle or a green circle on the screen (green circles are presented with a probability of 30%). He or she is required to shake the phone when a blue circle is presented (Go condition) but not when a green one is (No-Go condition). The reaction time it takes for the user to correctly shake the phone, as well as the number of failed trials are recorded (i.e., the user either does not shake the phone when a blue circle is presented, or shakes when a green circle is presented).

3. The *Trail Making Task* will provide a trail making test - part B with 13 dots denoted 1, A, 2, B… . First, the user will be presented with a set of screens, which give directions on how to correctly complete the test. Upon beginning a test, the participant will be presented with a 3-second countdown. At the completion of the countdown, a timer will start and the participant will be timed in tapping the circles in order (alternating between numbers and letters starting from 1). Upon tapping correct circles, a line will connect the circles showing the trail completed by the participant. The test can be cancelled at any time from the cancel button in the upper right.

The test will be randomly selected from a pre-generated list of tests, each of which when performed correctly produces a trail that does not cross itself. The circles will be roughly evenly distributed on the screen. Results, total time taken, number of mistakes, time between taps will be collected and recorded.

For information on the currently available ResearchKit active tasks, see <http://researchkit.org/docs/docs/ActiveTasks/ActiveTasks.html>

**Appendix A: THE MOOD DISORDER QUESTIONNAIRE**

Instructions: Please answer each question to the best of your ability.

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | Has there ever been a period of time when you were not your usual self and... | **YES** | **NO** |
| …you felt so good or so hyper that other people thought you were not your normal self or you were so hyper that you got into trouble? |  |  |
| …you were so irritable that you shouted at people or started fights or arguments? |  |  |
| …you felt much more self-confident than usual? |  |  |
| …you got much less sleep than usual and found you didn’t really miss it? |  |  |
| …you were much more talkative or spoke much faster than usual? |  |  |
| …thoughts raced through your head or you couldn’t slow your mind down? |  |  |
| …you were so easily distracted by things around you that you had trouble concentrating or staying on track? |  |  |
| …you had much more energy than usual? |  |  |
| …you were much more active or did many more things than usual? |  |  |
| …you were much more social or outgoing than usual: for example, you telephoned friends in the middle of the night? |  |  |
| …you were much more interested in sex than usual? |  |  |
| …you did things that were unusual for you or that other people might have thoughts were excessive, foolish, or risky? |  |  |
| …spending money got you or your family into trouble? |  |  |
| 2. | If you checked YES to more than one of the above, have several of these ever happened during the same period of time? |  |  |
| 3. | How much of a problem did any of these cause you – like being unable to work; having family, money or legal troubles; getting into arguments or fights? *Please circle one response only.*  No Problem Minor Problem Moderate Problem Serious Problem | | |
| 4. | Have any of your blood relatives (i.e. children, siblings, parents, grandparents, aunts, uncles) had manic-depressive illness or bipolar disorder? |  |  |
| 5. | Has a health professional ever told you that you have manic-depressive illness or bipolar disorder? |  |  |

**Appendix B: PATIENT HEALTH QUESTIONNAIRE – 9**

**(PHQ – 9)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Over the last 2 weeks, how often have you been bothered by any of the following problems?**  *(Use Circle to indicate your answer)* | | Not at all | Several  days | More  than half  the days | Nearly  Every  day |
| **1** Little interest or pleasure in doing things | | 0 | 1 | 2 | 3 |
| **2** Feeling down, depressed, or hopeless | | 0 | 1 | 2 | 3 |
| **3** Trouble failing or staying asleep, or  sleeping too much | | 0 | 1 | 2 | 3 |
| **4** Feeling tired or having little energy | | 0 | 1 | 2 | 3 |
| **5** Poor appetite or overeating | | 0 | 1 | 2 | 3 |
| **6** Feeling bad about yourself – or that you  are a failure or have let yourself or your  family down | | 0 | 1 | 2 | 3 |
| **7** Trouble concentrating on things, such as  reading the newspaper or watching  television | | 0 | 1 | 2 | 3 |
| **8** Moving or speaking so slowly that other  people could have noticed? Or the  opposite – being so fidgety or restless  that you have been moving around a lot  more than usual | | 0 | 1 | 2 | 3 |
| **9** Thoughts that you would be better off  dead or of hurting yourself in some way | | 0 | 1 | 2 | 3 |
|  | Add columns: \_\_\_\_\_\_\_+\_\_\_\_\_\_\_+\_\_\_\_\_\_  =Total Score: \_\_\_\_\_\_\_\_\_ | | | | |
| **If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?**   |  |  |  |  | | --- | --- | --- | --- | | **Not difficult at all** | **Somewhat difficult** | **Very difficult** | **Extremely difficult** | |  |  |  |  | | | | | | |

**Appendix C: Altman Self-Rating Mania Scale (ASRM)**

**Instructions:**

1. There are 5 statements groups on this questionnaire: read each group of statements carefully.
2. Choose the one statement in each group that best describes the way you have been feeling for the past week.
3. Check the box next to the number/statement selected.
4. Please note: The word “occasionally” when used here means once or twice; “often” means several times or more and “frequently” means most of the time.

**Question 1**

|  |  |
| --- | --- |
|  | **0 I do not feel happier or more cheerful than usual** |
|  | **1 I occasionally feel happier or more cheerful than usual** |
|  | **2 I often feel happier or more cheerful than usual.** |
|  | **3 I feel happier or more cheerful than usual most of the time** |
|  | **4 I feel happier or more cheerful than usual all of the time.** |

**Question 2**

|  |  |
| --- | --- |
|  | **0 I do not feel more self-confident than usual** |
|  | **1 I occasionally feel more self-confident than usual** |
|  | **2 I often feel more self-confident than usual.** |
|  | **3 I feel more self-confident than usual** |
|  | **4 I feel extremely self-confident all of the time.** |

**Question 3**

|  |  |
| --- | --- |
|  | **0 I do not need less sleep than usual** |
|  | **1 I occasionally need less sleep than usual** |
|  | **2 I often need less sleep than usual.** |
|  | **3 I frequently need less sleep than usual** |
|  | **4 I can go all day and night without any sleep and still not**  **feel tired.** |

**Question 4**

|  |  |
| --- | --- |
|  | **0 I do not talk more than usual** |
|  | **1 I occasionally talk more than usual** |
|  | **2 I often talk more than usual.** |
|  | **3 I frequently talk more than usual** |
|  | **4 I talk constantly and cannot be interrupted.** |

**Question 5**

|  |  |
| --- | --- |
|  | **0 I have not been more active (either socially, sexually, at**  **work, home or school) than usual.** |
|  | **1 I have occasionally been more active than usual** |
|  | **2 I have often been more active than usual.** |
|  | **3 I have frequently been more active than usual** |
|  | **4 I’m constantly active or on the go all the time** |