Protocol Title: Internet-based Cognitive Behavioral Therapy to Reduce Depressive Symptoms after Stroke Pilot/Feasibility Study

Short Title: Internet-based CBT for Depression after Stroke Pilot

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Brief Description:

Stroke is one of the leading causes of death and disability in the United States, with estimated direct and indirect costs exceeding 70 billion dollars per year. Depression is common after stroke, occurring in approximately 25% of all patients. Depression has been associated with lower quality of life, higher mortality, increased healthcare utilization and higher costs. Cognitive behavioral therapy (CBT) interventions have been shown, in small studies, to both treat and prevent the development of post-stroke depression. CBT based interventions therefore have the potential to improve quality of life and reduce healthcare costs after stroke. Unfortunately, there are significant barriers to the widespread use of CBT in the stroke population, including limited access to licensed providers, high costs of treatment, and limited mobility. Alternative methods for delivering CBT have the potential to improve access and reduce costs and may make widespread dissemination of CBT based treatment possible. We aim to test the feasibility of an internet-based CBT (iCBT) program combined with a telephone/email based coaching servive in patients with recent stroke. We will do this by partnering with Joyable. Joyable is an existing, commercially available iCBT program. Joyable's iCBT Program for Depression combines 42 brief online activities with a telephone/email based coaching service, which is designed to motivate and encourage individuals to complete the online modules.

Objectives:

1. Determine the feasibility of internet-based CBT in patients with recent ischemic stroke and depressive symptoms, by quantifying adherence to the program in a pilot population of 20 subjects.

2. Quantify changes in depressive symptoms and quality of life in subjects pre- and post-program participation, to provide preliminary evidence of the efficacy of internet-based CBT to improve outcomes after stroke.

Primary Outcome variables
The primary outcomes will be the number of activities in the iCBT program completed by participants and reduction in depressive symptoms, measured the 9-item Patient Health Questionnaire (PHQ-9).

Secondary Outcome variables
Secondary outcome variables will include: completion of the iCBT program, number of telephone/email based coaching interactions, quality of life, measured using the EuroQOL-5D

(EQ-5D), healthcare utilization, measured using the Stanford Health Care Utilization Survey, and subject satisfaction with the program.

Background

Depression after stroke

Depression is common after stroke, occurring in up to one-third of all stroke patients.[1] A recent American Heart Association (AHA) scientific statement on post-stroke depression highlighted the importance of this condition, noting that it was "under-recognized, under-investigated, and under-treated."[2] Individuals with depression after stroke have been shown to have lower functional status and lower quality of life than those without depression, irrespective of stroke severity, although the independent contribution of depression on outcomes is still not fully understood.

Traditional Cognitive Behavioral Therapy

Cognitive behavioral therapy (CBT) is an effective treatment for common mood disorders. Studies have shown a beneficial effect of CBT for both the treatment and prevention of depression after stroke.[3, 4] There is also evidence suggesting that CBT may provide a more durable and lasting treatment effect than pharmacotherapy with selective serotonin reuptake inhibitors.[5]

Despite the promise of CBT, its role in routine clinical practice is limited. There are significant barriers to widespread use of CBT. First, access to experienced CBT practitioners is limited.[6] Second, the time and travel requirements to complete a course of CBT, which may require 2-3 visits per week for 10-12 weeks, are onerous for many patients. This may be even more difficult for patients with mobility limitations, which are common after stroke. Third, the cost of CBT may be prohibitive, particularly if providers do not accept insurance.[6] Finally, patients may be resistant to in-person CBT because of stigma or fear of sharing deeply personal feelings with a therapist.

Technology and CBT

Technology provides an exciting alternative to traditional CBT.[6-8] Internet-based CBT has the potential to lower costs and improve accessibility. Internet-based CBT eliminates the challenges of finding a therapist and/or arranging transport to/from visits. There is also limited data to suggest that technology has the potential to reduce the stigma and fear associated with in-person therapy sessions, and subjects may actually be more likely to disclose symptoms when they believe they are interacting with a computer rather than a human.[9]

Although internet-based CBT interventions may provide a lower intensity of treatment than traditional in-person CBT, they still have the potential to be effective. An individual patient-data meta-analysis of 3876 subjects from 13 studies concluded that internet-based CBT is effective at treating depressive symptoms in general.[10] Encouragingly Internet use is now common among older adults in the U.S. The Pew Research Center reported that in 2016 87% of 50-64 year olds and 64% of adults 65 years or older use the Internet.[11] The few studies of internet-based CBT interventions among older adults have demonstrated their efficacy in reducing depressive symptoms among adults 50 years or older and among adults 45 years or older with cardiovascular disease (CVD) or risk factors for CVD.[12, 13 14] Thus, an Internet-based CBT intervention among stroke survivors has the potential to reduce depressive symptoms. However, because patients with stroke have experienced a structural brain injury and may have residual cognitive and physical disability, dedicated study within the stroke population is necessary.

Joyable: Internet-based CBT with personalized coaching
Joyable offers an iCBT program for Depression which is an 8-week, internet-based cognitive behavioral therapy (CBT) program for depression, developed alongside Robert DeRubeis PhD, a clinical psychologist with research expertise in the processes and outcomes of treatments for depression. Joyable users complete brief interactive modules (42 total activities) on a smartphone or computer. Most of these modules can be completed in 5-10 minutes and cover the core elements of CBT: psychoeducation, cognitive restructuring, and behavioral activation. In addition to its digital programs, users receive unlimited guidance and support from coaches via phone, text, and email. Coaches both respond to and proactively reach out to participants. They are trained extensively in motivational interviewing, with the goal of driving participants toward completion of the CBT program. Joyable's depression program has shown symptom reduction of 40%, as measured by the PHQ-9, with satisfaction and completion rates that exceed face-to-face therapy (unpublished data, from Joyable).

Joyable monitors the subjects' mood through weekly assessments of the PHQ-9. There are built-in escalation protocols, designed with Dr. Lanny Berman, the former President of the American Association for Suicidology. Joyable identifies safety risks both through its software and through extensive training of coaches. All coaches are trained with how to respond to at-risk clients, including providing emotional support and informing clients about appropriate resources to support them, including the National Suicide Prevention Lifeline and Crisis Text Line. In urgent cases, Joyable can also connect clients with a licensed professional by phone.

Study Design

Design: A pilot single arm clinical trial is proposed. Adults (18 years or older) with ischemic stroke will be enrolled within 6~~3~~ months of their event. All subjects will be enrolled in Joyable's iCBT program for Depression.

Duration: The study will plan to enroll 20 subjects. Each subject will be in the study for 90 days. The project will begin immediately after IRB approval. The study is expected to take approximately 1 year to complete.

Resources for human research protection: The clinical research section of the comprehensive stroke center at the University of Pennsylvania will conduct the study. This team has extensive experience conducting both observational and interventional studies in stroke patients. The clinical research team consists of four full time clinical research coordinators, 1 nurse practitioner, 3 vascular neurology fellows, 2 vascular neurology research fellows, and 7 vascular neurology attendings. All members of the clinical research team will be required to complete CITI training and maintain up to date certification while the study is underway. The research team will maintain training records, including copies of all pertinent certificates. Prior to initiation of the study, the research team will have an in-service session to review the study protocol and procedures in detail. While the study is underway, the research team will meet weekly to discuss the study, including enrollment, follow-up, and any other issues which may arise. Dr. Mullen will be primarily responsible for overseeing the study.

Target Population: Adult patients hospitalized with ischemic stroke within the past 6~~3~~ months.

Inclusion Criteria:

- Age ≥18 years of age
- Acute ischemic stroke within the past 6~~3~~ months

- Regular access to the internet, sufficient to allow a minimum of interactions with the internet daily, either through a personal smartphone or web-based internet browser.
- Subject is willing and able to participate in internet-based cognitive behavioral therapy
- Can participate in the program in English
- Willingness and ability to sign informed consent by the patient
- Symptoms of mild to moderately depressed mood, defined as a score of 5-19 on the Patient Health Questionnaire-9 at the time of study enrollment.

Exclusion Criteria

- Severely depressed patients, defined by a score of 20+ on the Patient Health Questionnare-9 are excluded
- Patients with an active bipolar disorder diagnosis are excluded
- Patients with personality disorder diagnoses are excluded
- Patients with active suicidality or past suicide attempts are excluded
- History of schizophrenia or schizoaffective disorder
- Active participation in face-to-face psychotherapy prior to stroke
- Patients with a history of dementia are excluded
- Patients with aphasia, defined as a score of 1 or greater on NIH Stroke Scale Item 9 are excluded.
- Patients without regular internet access through a computer, tablet or smartphone are excluded.
- Subjects requiring long-term inpatient nursing care are excluded. For patients enrolled as inpatients, individuals being discharged to both home and acute rehab are eligible. Individuals being discharged to a skilled nursing facility or hospice are excluded.
- Expected life expectancy less than 6 months or other inability to comply with study follow-up.
- Pregnant women and prisoners are excluded

Vulnerable populations: Children, pregnant women, fetuses, neonates, and prisoners are not included in this research study.

Sample Size: 20 subjects will be enrolled.

Accrual: The comprehensive stroke center at the Hospital of the University of Pennsylvania (HUP) is a tertiary referral center for acute ischemic stroke, with annual case volumes of approximately 600 strokes per year on the inpatient stroke service. Additionally, the stroke team sees patients in the outpatient clinic both in follow-up from their acute hospitalization and in consultation to provide second opinions for patients treated elsewhere. Due to the broad inclusion criteria of this study, it is expected that many of the patients seen, both inpatient and outpatient, will be eligible for participation in this study. We expect that we will be able to enroll 1-2 patients per week and will complete enrollment within 6 months.

Recruitment: A stroke physician evaluates all patients with acute ischemic stroke who present to HUP. All stroke team physicians will be trained investigators in this study, and they will screen patients for eligibility during routine clinical care. Study physicians will also screen for potentially eligible subjects during outpatient clinic sessions. All eligible subjects will be informed of the study, and if they are interested in participation, a study physician will obtain informed consent. The original signed consent form will be kept in the study binder. A copy of

the signed consent form will be given to the patient and another copy will be placed in the medical record.

Procedures

Consent: A member of the study team will approach eligible patients. The consent form will be described in plain language. The patient will be given a hard copy of the consent form for their reference. Written informed consent will be obtained. Judgements about capacity to provide informed consent will be made by the physicians caring for the patient and the person obtaining informed consent. All patients with acute ischemic stroke received detailed neurologic assessments, including assessments of cognition, language function, neglect/anosognosia, and other domains of neurologic function. Additionally, during the consent process the subject will be asked open-ended questions about the study such as: "Would you explain to me what you think we are asking you to do?" and "what are the possible benefits and risks to you of participating in this study?" If either the clinical team feels that the patient cannot provide informed consent, or the patient's responses to these open-ended questions fail to demonstrate sufficient comprehension to provide informed consent, in the judgment of the investigator, the patient will be excluded from participation. The subject will have the ability to withdraw consent at any time.

Study Procedures:

Baseline

After consent is obtained, the Patient Health Questionnaire-9 (PHQ-9)[15] will be administered to the subject. This is a simple, 9-item survey which has been validated to identify depression after stroke. Patients who score between 5-19 inclusive will be enrolled in the study. Subjects who score 0-4 or 20+ will receive education about post-stroke mood disorders and local psychiatry/psychology resources, including the contact information for regional crisis centers, but will not be enrolled. Subjects who screen 20+ will have their attending physician notified so that appropriate referrals or treatments can be initiated by the clinical team.

For patients who are enrolled, basic demographic and clinical information will be collected including: age, sex, race/ethnicity, past medical history (including history of hypertension, hyperlipidemia, coronary artery disease, chronic kidney disease, prior history of TIA/Stroke, prior history of anxiety, depression, or PTSD, other medical history), educational attainment, insurance status, marital status, number of people living in the home, medication history (current/prior use of an antidepressant medication), current/prior participation in psychotherapy or counseling for mental health problems, tobacco history (current smoker, former smoker, never smoker), alcohol use history (current alcohol use yes/no and if yes, number of drinks per week), stroke location, stroke mechanism (large vessel atherosclerosis, small vessel disease, cardioembolism, other, cryptogenic), discharge disposition (home, acute rehab).

Additional assessments will include the NIHSS, a structured neurologic examination used to quantify neurologic deficits,[16, 17], modified Rankin Scale,[18] the Patient Health Questionnaire-9 (PHQ-9) to assess mood,[15] and the abbreviated Duke Social Support Index.[19] We will also ask the subject a series of questions regarding availability of internet and mobile device usage, including how they interact with the internet and frequency of internet use (See attached appendix).

After baseline data collection, the subjects will be enrolled in Joyable's iCBT program. For subjects who would like to participate in the program using their smartphone, the CBT application will be installed on their device and they will be encouraged to complete the initial

evaluation and activities at the time of enrollment. Subjects without their own devicewill be enrolled via a study specific tablet using the web-interface. Subjects will be given their login information and information on how to access the program via the internet and install the program on their mobile device. Subjects will be asked to complete the initial evaluation and CBT activities at the time of enrollment.

Joyable is a commercially available 8-week program that consists of 5-6 online activities per week, for a total of 42 activities. Most activities can be completed within approximately 5-10 minutes. Activities cover the core elements of CBT: psychoeducation, cognitive restructuring, and behavioral activation. In addition to the digital program, as a part of the Joyable product, all participants will be assigned a coach. The role of the coach is to provide accountability, motivation, emotional support, and guidance, leading clients to get the most out of the iCBT program. They provide this support through a combination of phone, text, and email interactions determined by the client. Joyable coaching is defined by 3 pillars: Motivational Interviewing (MI), Program Knowledge, and Client Experience. All coaches are trained to competency in MI, an evidence-based method for structuring conversations to harness a person's intrinsic motivation to change. MI has been shown to increase engagement and improve client outcomes. Coaches attend a rigorous 1-month training course, biweekly booster sessions, and submit tapes of client communications until they reach competency. In addition to MI, coaches are trained in the iCBT program and how to support clients with obstacles that may arise and effectively deliver program knowledge to drive client success. At the time of study enrollment, we will assist the subject in scheduling their first contact with their assigned coach.

72 Hour Telephone Encounter
Subjects will be contacted by the study team in person or by telephone 72+/- 24 hours after enrollment to troubleshoot any technical difficulties accessing the Joyable program.

30 Day Telephone Encounter
Subjects will be contacted by the study team phone or in person at 30 days +/-7 days after enrollment to assess technical difficulties using the Joyable program, functional status using the modified Rankin scale, and quality of life using the Euroqol EQ-5D.

90 Day In-person Visit
Subjects will be seen by the study team 90 days +/- 14 days after enrollment to assess their neurologic function using the NIHSS, mood using the PHQ-9, functional status using the modified Rankin Scale, Quality of life using the Euroqol EQ-5D,[20, 21] healthcare utilization using the Stanford Health Utilization survey,[22] whether any other treatment for mental health problems was received (including medication and psychotherapy) and perceived utility of Joyable iCBT for depression as well as perceived barriers to successful use of internet-based CBT.

Table 1. Study measures and timing of assessment

	Baseline	72 hr Call	30 day call	90 day visit
Demographics	X			
Stroke information	X			
SSRI Use	X		X	X
Assess for technical problems		X	X	
NIHSS	X			X
mRS	X		X	X
EQ-5D	X		X	X
SHU				X
PHQ-9	X			X
Semi-Quantitative assessment of perceptions about Internet-based CBT				X

NIHSS=National Institute of Health Stroke Scale, EQ-5D=Euro-Qol 5D, SHU=Stanford Health Utilization survey, PHQ-9=Patient Health Questionnaire 9,

Analysis Plan

The baseline demographic variables of the study population will be summarized using means, medians, and proportions as appropriate. For each subject, we will calculate the total amount of time spent interacting with the Joyable program and the total number of Joyable activities that the patient successfully completed. We will then calculate averages across the study population. These metrics will provide important information on the average "dose" of CBT received. In an exploratory analysis we will look for relationships between baseline clinical and demographic factors and number of activities completed.

We will calculate the average PHQ-9 score at enrollment and 90 days. We will compare the PHQ-9 score from enrollment to day 90. The statistical power of this test is uncertain. In Table 2 we present estimated study power (with α=0.05) across a range of assumptions about both the change in PHQ-9 over time and the standard deviation of the difference in PHQ-9 over time. These calculations show that although this is a small pilot study, we have >80% power to detect a difference in PHQ-9 of 3 or more points across a range of assumptions. The PHQ-9 will also be administered to subjects weekly via through the Joyable program. We will examine whether there are significant changes in score over time using repeated measures analysis (generalized estimating equations, GEE) with PHQ-9 score as the dependent variable and week as the independent variable.

In an exploratory analysis, we will divide patients into two groups based on PHQ-9 at study completion (*high depression symptoms*, defined as median or above and *low depression*

symptoms, defined as below the median score). Healthcare outcomes, including modified Rankin scale, health related quality of life, and healthcare utilization will be compared across groups. We hypothesize that patients with high depression symptoms will have worse functional outcome, lower quality of life, and higher healthcare utilization. We will also divide patients into groups based on their participation in the Joyable program and compare outcomes (e.g., PHQ-9 score, quality of life, health utilization) between subjects who showed high engagement in the program and those who showed low engagement.

Table 2. Statistical Power for single sample paired t-test

SD of the Difference	Difference in PHQ-9 Pre/Post Treatment				
	1	2	3	4	5
2	61%	99%	100%	100%	100%
3	32%	85%	99%	100%	100%
4	20%	61%	92%	99%	100%
5	15%	43%	77%	95%	99%
6	12%	32%	61%	85%	96%

Data Confidentiality

Internet-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Paper-based records will be kept in a locked, secure location and only accessible to study personnel. Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information. Whenever feasible, identifiers will be removed from study-related information.

No clinical information obtained by the research team will be sent to Joyable. De-identified data from Joyable will be sent to the research team, which will include the number of Joyable activities completed by the subject, the number coaching interactions, and results of Joyable administered PHQ-9 and satisfaction assessments. This data will be organized by subject identification number, which can be used to link to the data collected by the research team. The research team will maintain a password protected file on a secured computer at the University of Pennsylvania which will link subject identification number to identifying information for each subject (name, medical record number, date of birth). Access to this file at the University of Pennsylvania will be limited to the PI and the study research coordinator. A Microsoft Excel document will be created which will include subject name, date of birth, and study identifier. This document will be uploaded to Penn+Box. The study team at Joyable will be given access to the file via Penn+Box. They will use this information to link the Joyable data elements described above to each subject. Joyable will then upload a Microsoft Excel file containing this data and subject identifier to the study Penn+Box, where it will be downloaded by the research team.

Patients who enroll in the study will all participating in Joyable's iCBT Program for Depression. During enrollment in the study, patients will create an account with Joyable. As a part of this process, subjects register with Joyable using the same process as they currently use for their commercially available program. Registration requires the subject to submit the following PHI: name, date of birth, gender, and email address. Access to PHI will be limited to those who need it. This may include the individual coach who is assigned to each subject, coach managers who have access to subject data for the coaches that report to them, Joyable's analytic team which

has access to data for the purpose of aggregating and sharing back results to the research team, and a small number of engineers who can access data in order to troubleshoot bugs in the software. Subject interactions with Joyable will be governed by Joyable's existing Privacy Policy (see https://joyable.com/privacy) and terms of use (see https://joyable.com/terms). Additionally, subjects will be given the option to opt in or out of email and text based coaching services. Joyable encrypts the transmission of personal information or uses Secure Socket Layer technology when possible. Joyable does not encrypt the transmission of text or email communication. This is made clear to the subject at the time of opt-in:

An important note on privacy:

Your privacy is important to us. Text messages and emails from your coach are not encrypted while in transit. To reduce the chance that your information is seen by the wrong recipient, we suggest you enable the highest security measures on your personal device (pass codes, strong passwords, 2 step authentication, etc). Taking these precautions will not eliminate all risks associated with communications sent in unencrypted text messages or email.

By checking the box above, you are agreeing to the risks associated with unencrypted text and email and consent to communicating with your Joyable coach through text and email, or Skype and email if you live outside of the United States.

Joyable meets or exceeds all federal requirements for protecting personal health information (PHI) of individuals under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All Joyable services operate behind a virtual private cloud with dedicated instances, and Joyable encrypts all PHI both in transit and at rest. Access to sensitive information is limited to Joyable employees directly involved with supporting any given client. Joyable participates in regular security assessments of both its processes and technology.

Subject Confidentiality

All data recorded will be kept in a spreadsheet that is managed by a member of the study team. This excel spreadsheet will be password protected and we will ensure that the access to this database is secured. Subjects will be coded using a study identification number that is detached from the patient's name and recorded into a separate excel spreadsheet. All study related paper files will be stored in a locked cabinet and accessible only by research staff. No published or presented materials will identify subjects by names, initials, or other means. The data set will be password protected and only accessible to the study team. If needed for future research this dataset will not be used without prior IRB approval.

Subject Privacy and Protected Health Information/Data Protection

The following protected health information (PHI) will be collected:

- Name
- Date of birth
- Medical record number

This data will be recorded and secured as detailed above.

Joyable meets or exceeds all federal requirements for protecting personal health information (PHI) of individuals under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All Joyable services operate behind a virtual private cloud with dedicated instances, and Joyable encrypts all PHI both in transit and at rest. Access to sensitive information is limited to Joyable employees directly involved with supporting any given client. Joyable participates in regular security assessments of both its processes and technology.

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Appendix

1. Screening PHQ-9
2. Baseline CRF
3. 72 Hour Call CRF
4. 30 Day Call CRF
5. 90 Day Visit CRF

1. Screening PHQ-9

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME:_____ DATE:_____

Over the last 2 *weeks*, how often have you been bothered by any of the following problems?
(use "✓" 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 falling 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 figety 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	0	1	2	3
		add columns	+	+

(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card). TOTAL:

10. 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	_____

NOTE: SUBJECTS MUST SCORE BETWEEN 5-19, INCLUSIVE, TO BE ENROLLED

2. Baseline Study CRF (FOR ENROLLED PATIENTS ONLY):

1. **Subject ID #:** ___ ___ ___

2. **Enrolling Investigator:** _____

3. **Age:** __ __ __

4. **Sex:** Male ☐ Female ☐

5. **Race**: **(Check one)**
   Caucasian ☐
   African American ☐
   Asian ☐
   American Indian or Alaskan Native ☐
   Other ☐

6. **Ethnicity**: ☐ Not Hispanic/Latino ☐ Hispanic/Latino

7. **Educational attainment**
   - ☐ Less than 9th grade
   - ☐ 9-11th grade (includes 12th grade with no diploma)
   - ☐ High school graduate/GED or equivalent
   - ☐ Some college or AA degree
   - ☐ College graduate or above
   - ☐ Refused

8. **Health insurance** (select all that apply)
   - ☐ Medicare
   - ☐ Medicaid
   - ☐ Veteran's Health Administration
   - ☐ Private
   - ☐ Other
   - ☐ No insurance

9. **Symptom onset:** ☐ Witnessed onset ☐ Last known normal

   Date: __ __ (month) /__ __ (day) / 2 0 __ __ **Time** __ __ : __ __
   hr hr min min

10. **Medical History/Risk Factors:** **(Check all that apply)**

a. Hypertension	No ☐ Yes ☐
b. Diabetes	No ☐ Yes ☐
c. CAD	No ☐ Yes ☐
d. Atrial Fibrillation	No ☐ Yes ☐
e. CHF	No ☐ Yes ☐
f. Prior TIA	No ☐ Yes ☐
g. Prior Stroke	No ☐ Yes ☐
h. Prior Anxiety	No ☐ Yes ☐

i. Prior Major Depressive Episode No ☐ Yes ☐
j. Prior PTSD No ☐ Yes ☐
l. Other (Please List):

11. **Tobacco** Never ☐ Former ☐ Current ☐

12. **Current Alcohol** No ☐ Yes ☐

If Yes, number of drinks per week: __ __

13. **Marital Status:**

☐ Currently Married
☐ Divorced
☐ Widowed
☐ Never Married

14. **Number of People that you currently live with: __ __**

15. **Were you working prior to this stroke?**

No ☐ Part Time ☐ Full Time ☐

16. **Prior to the stroke, were you ever on a prescription medication for anxiety, depression, or PTSD?**

No ☐ Yes ☐

If Yes, please list: _____

17. **Prior to the stroke did you ever participate in psychotherapy or counseling with a therapist?**

No ☐ Yes ☐

18. **Stroke Location (check all that apply):**

☐ Right hemisphere
☐ Left hemisphere
☐ Posterior circulation
☐ Cortical
☐ Subcortical

19. **Vascular Territory of Stroke (check all that apply)**

☐ ACA

☐ MCA
☐ PCA
☐ ICA
☐ Vertebral/Basilar

20. **Stroke Etiology:**

Free Text Description: _____

Stroke etiology at discharge (TOAST Criteria):

☐

Large Vessel Stenosis ☐
Lacunar ☐
Cryptogenic ☐
Other: _____ ☐

21. **Discharge Disposition from Acute Hospitalization**

Home ☐
Acute Rehabilitation facility ☐

22. **Is the subject currently on pharmacotherapy for depression? (Review current medications)**

☐ No
☐ Yes

If Yes, please list and select category from below: _____

☐ SSRI
☐ SNRI
☐ TCA
☐ Other

23. Abbreviated Duke Social Support Scale

Question	Answer		
Number of family members within 1 hour that you can depend on or feel close to?	None (1)	1-2 people (2)	More than 2 people (3)
Number of times in the past week in which you spent time with someone not living with you?	None (1)	1-2 times (2)	More than 2 times (3)
Number of times in the past week that you talked with friends/relatives on the telephone?	0-1 times (1)	2-5 times (2)	More than 5 times (3)
Number of times in the past week that you attended meetings of clubs, religious groups, or other groups that you belong to (other than at work)?	0-1 times (1)	2-5 times (2)	More than 5 times (3)
Do family and friends understand you?	Hardly ever (1)	Some of the time (2)	Most of the time (3)
Do you feel useful to family and friends?	Hardly ever (1)	Some of the time (2)	Most of the time (3)
Do you know what is happening with family and friends?	Hardly ever (1)	Some of the time (2)	Most of the time (3)
Do you feel listened to by family and friends?	Hardly ever (1)	Some of the time (2)	Most of the time (3)
Do you feel you have a definite role in family and among friends?	Hardly ever (1)	Some of the time (2)	Most of the time (3)
Can you talk about your deepest problem?	Hardly ever (1)	Some of the time (2)	Most of the time (3)
How satisfied are you with relationships with family and friends?	Very dissatisfied (1)	Somewhat dissatisfied (2)	Satisfied (3)

24. **NIHSS**

Date: __ __ /__ __ / 2 0 __ __
month day year

1a. Level of consciousness 0 alert 1 drowsy 2 stuporous 3 coma 1b. LOC questions (month, age) 0 both correct 1 one correct 2 incorrect 1c. LOC commands (close eyes, make a fist) 0 both correct 1 one correct 2 incorrect 2. Best gaze 0 normal 1 partial gaze palsy 2 forced deviation 3. Visual fields 0 no visual loss 1 partial hemianopia 2 complete hemianopia 3 bilateral hemianopia 4. Facial palsy 0 normal 1 minor 2 partial 3 complete 5. Motor arm a. Left arm 0 no drift 1 drift 2 can't resist gravity 3 no effort against gravity 4 no movement Z amputation/joint fusion b. Right arm 0 no drift 1 drift 2 can't resist gravity 3 no effort against gravity 4 no movement Z amputation/joint fusion	6. Motor leg a. Left leg 0 no drift 1 drift 2 can't resist gravity 3 no effort against gravity 4 no movement Z amputation/joint fusion b. Right leg 0 no drift 1 drift 2 can't resist gravity 3 no effort against gravity 4 no movement Z amputation/joint fusion 7. Limb ataxia (FNF, HKS) 0 absent 1 present in one limb 2 present in 2 limbs 8. Sensation (pin) 0 normal 1 partial loss 2 severe loss 9. Best language 0 no aphasia 1 mild-mod aphasia 2 severe aphasia 3 mute 10. Dysarthria 0 none 1 mild-mod 2 near to unintelligible or worse/mute Z intubated/barrier 11. Extinction and inattention 0 no neglect 1 partial neglect 1. complete neglect **Total Score: _____**

25. **Modified Rankin Scale**

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

TOTAL (0–6): _____

26. **Euro-QOL-5D**

Please indicate which statements best describe your own health state today.

Mobility

____I have no problems in walking about
____I have some problems in walking about
____I am confined to bed

Self-Care

____I have no problems with self-care
____I have some problems washing or dressing myself
____I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

____I have no problems with performing my usual activities
____I have some problems with performing my usual activities
____I am unable to perform my usual activities

Pain/Discomfort

____I have no pain or discomfort
____I have moderate pain or discomfort
____I have extreme pain or discomfort

Anxiety/Depression

____I am not anxious or depressed

____I am moderately anxious or depressed
____I am extremely anxious or depressed

Visual Analogue Scale

Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box to the point on the scale that indicates how good or bad your health state is today.

Your own health state today

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

27. **Internet/Mobile Device Usage**

How do you access the internet? (Select all that apply):

- ☐ Computer
- ☐ Tablet
- ☐ Smart Phone

What is your preferred method of internet access? (Select 1):

- ☐ Computer
- ☐ Tablet
- ☐ Smart Phone

Where do you typically access the internet? (Select all that apply):

- ☐ Work
- ☐ Home
- ☐ Friend/Family member's home
- ☐ Public access point (i.e. Library, coffee shop, etc)
- ☐ Other: _____

Where is your preferred location to access the internet? (Select 1):

- ☐ Work
- ☐ Home
- ☐ Friend/Family member's home
- ☐ Public access point (i.e. Library, coffee shop, etc)
- ☐ Other: _____

How often do you typically access the internet? (Select 1):

- ☐ More than once a day
- ☐ Once a day
- ☐ Every couple of days
- ☐ Once a week or less

How much time per day do you typically spend on the internet?

- ☐ <30 minutes
- ☐ 30-59 minutes
- ☐ 60-119 minutes
- ☐ 120+ minutes

If you have a smartphone or tablet, do you use "Apps?"

- ☐ No
- ☐ Yes
- ☐ Not Applicable - do not own a smartphone or tablet

If you have a smartphone or tablet, do you ever have problems using it (e.g. typing, reading, using the touchscreen)?

- ☐ No
- ☐ Yes
- ☐ Not Applicable - do not own a smartphone or tablet

Have you ever used an "App," website, or online platform to improve your health before?

☐ No
☐ Yes

If yes, how would you rate the experience?

☐ Not helpful
☐ Somewhat helpful
☐ Very helpful
☐ Not applicable

3. **72-Hour Phone Call**

Date: __ __ / __ __ / __ __ __ __
dayday year year

Does the patient have difficulty accessing Joyable? No [0]☐ Yes [1]☐
If yes, please specify what the problem was and how it was addressed:

_____
_____

Name of the person who completed 48 hour follow up:
_____

Signature: _____

Date: __ __ / __ __ / __ __ __ __
month day year

4. **30-Day Phone Call**

Date: __ __ / __ __ / __ __ __ __
dayday year year

Does the patient have difficulty accessing Joyable? No [0]☐ Yes [1]☐
If yes, please specify what the problem was and how it was addressed:

_____
_____

Name of the person who completed 48 hour follow up:
_____

Signature: _____

Date: __ __ / __ __ / __ __ __ __
month day year

1. **Is the subject currently on pharmacotherapy for depression? (Review current medications)**

☐ No
☐ Yes

If Yes, please list and select category from below: _____

☐ SSRI
☐ SNRI
☐ TCA
☐ Other

2. Modified Rankin Scale

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

TOTAL (0–6): _____

2. Euro-QOL-5D

Please indicate which statements best describe your own health state today.

Mobility

____I have no problems in walking about
____I have some problems in walking about
____I am confined to bed

Self-Care
____I have no problems with self-care
____I have some problems washing or dressing myself
____I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities)*
____I have no problems with performing my usual activities
____I have some problems with performing my usual activities

____I am unable to perform my usual activities

Pain/Discomfort
____I have no pain or discomfort
____I have moderate pain or discomfort
____I have extreme pain or discomfort
Anxiety/Depression
____I am not anxious or depressed
____I am moderately anxious or depressed
____I am extremely anxious or depressed

Visual Analogue Scale

Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box to the point on the scale that indicates how good or bad your health state is today.

Your own health state today

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

5. 90 Day Visit

Date: __ __ /__ __ / 2 0 __ __
month day year

1. Is the subject currently on medications for depression? (Review current medications)

☐ No
☐ Yes

If Yes, please list and select category from below: _____

☐ SSRI
☐ SNRI
☐ TCA
☐ Other

2. Since enrolling in this study did you participate in psychotherapy or counseling with a therapist <u>OTHER THAN</u> what was provided through Joyable?

☐ No
☐ Yes

3. Are you currently working? No ☐ Part Time ☐ Full Time ☐

3. NIHSS

1a. Level of consciousness 0 alert 1 drowsy 2 stuporous 3 coma 1b. LOC questions (month, age) 0 both correct 1 one correct 2 incorrect 1c. LOC commands (close eyes, make a fist) 0 both correct 1 one correct 2 incorrect 2. Best gaze 0 normal 1 partial gaze palsy 2 forced deviation 3. Visual fields 0 no visual loss 1 partial hemianopia 2 complete hemianopia 3 bilateral hemianopia 4. Facial palsy 0 normal 1 minor 2 partial 4 complete 5. Motor arm a. Left arm 0 no drift 1 drift 2 can't resist gravity 3 no effort against gravity 4 no movement Z amputation/joint fusion b. Right arm 0 no drift 1 drift 2 can't resist gravity 3 no effort against gravity 4 no movement Z amputation/joint fusion	6. Motor leg a. Left leg 0 no drift 1 drift 2 can't resist gravity 3 no effort against gravity 4 no movement Z amputation/joint fusion b. Right leg 0 no drift 1 drift 2 can't resist gravity 3 no effort against gravity 4 no movement Z amputation/joint fusion 7. Limb ataxia (FNF, HKS) 0 absent 1 present in one limb 2 present in 2 limbs 8. Sensation (pin) 0 normal 1 partial loss 2 severe loss 9. Best language 0 no aphasia 1 mild-mod aphasia 2 severe aphasia 3 mute 10. Dysarthria 0 none 1 mild-mod 2 near to unintelligible or worse/mute Z intubated/barrier 11. Extinction and inattention 0 no neglect 1 partial neglect • complete neglect **Total Score: _____**

3. Modified Rankin Scale

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

TOTAL (0–6): _____

4. Euro-QOL-5D

Please indicate which statements best describe your own health state today.

Mobility

____I have no problems in walking about
____I have some problems in walking about
____I am confined to bed

Self-Care

____I have no problems with self-care
____I have some problems washing or dressing myself
____I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

____I have no problems with performing my usual activities
____I have some problems with performing my usual activities
____I am unable to perform my usual activities

Pain/Discomfort

____I have no pain or discomfort
____I have moderate pain or discomfort
____I have extreme pain or discomfort

Anxiety/Depression

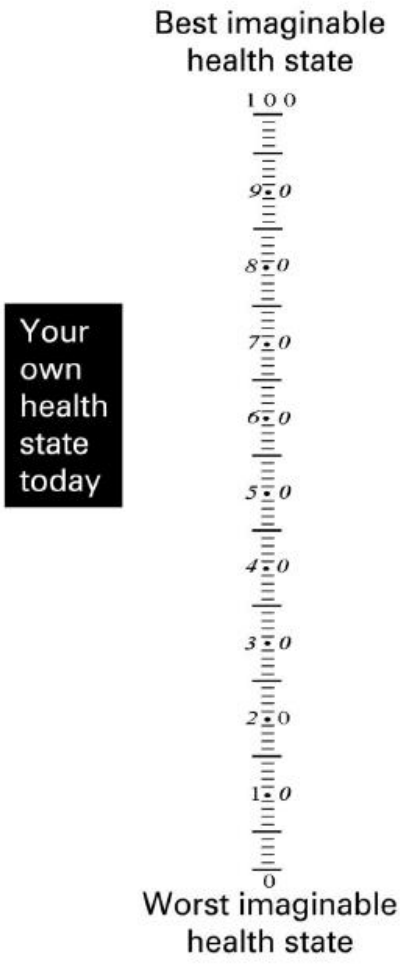
____I am not anxious or depressed
____I am moderately anxious or depressed
____I am extremely anxious or depressed

Visual Analogue Scale

Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box to the point on the scale that indicates how good or bad your health state is today.



Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

5. Healthcare Utilization

Since *study enrollment*:

How many times did you visit a **physician**? Do **not** include visits while in the hospital or to a hospital emergency room. Fill in with "0" or another number.	_____ times
How many times did you go to a **hospital** emergency room? Fill in with "0" or another number.	_____ times
How many different **times** did you stay in a hospital **overnight** or longer in the past 6 months? Fill in with "0" or another number.	_____ times
How may total **nights** did you spend in the hospital? Fill in with "0" or another number.	_____ nights

6. PHQ-9

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME:_____ DATE:_____

Over the last *2 weeks*, how often have you been bothered by any of the following problems?
(use "✓" 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 falling 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 figety 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	0	1	2	3
add columns		+	+	
(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card). TOTAL:				

10. 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	_____

7. Semi-Quantitative Assessment of iCBT Program:

Was joyable easy to use?

Extremely Difficult	Difficult	Neutral	Easy	Extremely Easy
1	2	3	4	5

How satisfied were you with Joyable activities?

Extremely Dissatisfied	Dissatisified	Neutral	Satisfied	Extremely Satisfied
1	2	3	4	5

How satisfied were you with your Joyable coach?

Extremely Dissatisfied	Dissatisified	Neutral	Satisfied	Extremely Satisfied
1	2	3	4	5

Was Joyable helpful with your home and/or work life?

Not Helpful	Slightly Helpful	Moderately Helpful	Very Helpful	Extremely Helpful
1	2	3	4	5

What did you like best about the Joyable program?

What about the Joyable program could be improved?

Would you recommend the program to other people with stroke?

[ ] Yes **[ ] No**

Why/Why Not?