“SMART-FM”: Smart-Phone Based Digital Therapeutic for Management of Fibromyalgia

Investigational Device:	Digital ACT
Protocol Date:	January 10, 2021
Protocol Number:	Swing-004
NCT Number:	NCT05005351
Sponsor:	Swing Therapeutics San Francisco, CA

STUDY SYNOPSIS

<table>
<tr><td>Study Number:</td><td>Swing-004</td></tr>
<tr><td>Protocol Title:</td><td>Smart-Phone Based Digital Therapeutic for Management of Fibromyalgia</td></tr>
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<tr><td>Study Sponsor:</td><td>Swing Therapeutics</td></tr>
<tr><td>Study Device:</td><td>Digital ACT</td></tr>
<tr><td>Study Phase:</td><td>II</td></tr>
<tr><td>Indications for Use:</td><td>Management of Fibromyalgia</td></tr>
<tr><td>Study Objectives:</td><td>The objectives of this study are to:
1. Assess the effect size between two digital therapies in the treatment of fibromyalgia over 12 weeks;
2. Assess the feasibility of conducting a largely virtual clinical study in a fibromyalgia population.</td></tr>
<tr><td>Study Description:</td><td>This is a blinded hypothesis, multicenter, randomized, active-controlled, non-significant risk study.

The study has a two-arm parallel group design:
● Digital Acceptance and Commitment Therapy (ACT) Arm (Group A): Study subjects receive standard of care + Digital ACT
● Digital Symptom Tracker Arm (Group S): Study subjects receive standard of care + a daily symptom and function tracker as well as access to digital fibromyalgia education.

Qualified subjects have a diagnosis of fibromyalgia (FM) as defined by the 2016 ACR classification criteria and no other significant pain disorders that could compromise the ability to assess changes in their FM symptoms. Qualified subjects may remain on a stable dose and regimen of concomitant therapy for FM.</td></tr>
<tr><td>Study Procedures:</td><td>The study will consist of the following visit/data collection timepoints

<table>
<tr><th>Type of Visit</th><th>Timing of Visit</th><th>Location of Visit</th></tr>
<tr><td>Visit C1:
Screening</td><td>Day -14 to 1</td><td>Clinic Visit</td></tr>
<tr><td>Baseline Data Collection Period</td><td>At least 6 days and no more than 14 days</td><td>Remote</td></tr>
<tr><td>Visit C2:
Baseline</td><td>Day 1</td><td>Videoconference or Clinic Visit</td></tr>
<tr><td>Check-in
C3, C4, C5</td><td>Weeks 2, 4 and 8</td><td>Telephonic or Videoconference</td></tr>
<tr><td>Visit C6 or C-ET
Final Appointment or Early Termination</td><td>Week 12 or ET</td><td>Videoconference or Clinic Visit</td></tr>
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	After the minimum 6-day baseline period, subjects will be randomized to: 1. **Digital ACT Arm (Group A):** Study subjects receive standard of care + Digital ACT 2. **Digital Symptom Tracker Arm (Group S):** Study subjects receive standard of care + a daily symptom and function tracker as well as access to digital fibromyalgia education.
Number of Sites and Subjects:	The study will be recruited from up to 10 North American sites.
Key Study Entry Criteria:	**<u>Key Inclusion criteria:</u>** 1. Subject is 22 to 75 years of age, inclusive 2. Subject has a diagnosis of primary FM as defined by the 2016 American College of Rheumatology Preliminary Diagnostic Criteria for FM 3. Subject with ongoing treatments should be on stable therapy for 30 days prior to screening appointment. 4. Subject is capable of reading and understanding English and has provided written informed consent to participate. **<u>Key Exclusion criteria</u>** 1. Lifetime history of bipolar disorder as assessed by the MINI. 2. Current, untreated, major depressive episode and/or anxiety disorders as assessed by the MINI. 3. Subject has a BDI-II total score > 25 at either the Screening appointment or Baseline appointment. 4. The subject is at increased risk of suicide on the basis of the investigator's judgment, a response > 1 to BDI item #9, or the results of the Columbia-Suicide Severity Rating Scale ("C-SSRS") conducted at Screening or Baseline (i.e., any suicidal behavior during the preceding year or C-SSRS Type 3, 4, or 5 suicidal ideation during the preceding year). 5. Subject has any other disease or medical condition that, in the opinion of the Investigator or Sponsor, could endanger the subject, interfere with the evaluation of the study device's efficacy or safety, or compromise the subject's ability to comply with/complete the study. **<u>Randomization criteria</u>** **Assessed at the Baseline Virtual appointment:** Only those subjects meeting all the following randomization criteria at the Baseline-appointment are eligible for randomization: 1. The subject continues to meet all inclusion and exclusion criteria 2. The subject is familiar and compliant with the digital therapeutic application (has completed four daily training sessions within the app) 3. The subject is sufficiently symptomatic as assessed by weekly pain scores:

	a. A mean pain intensity score ≥4 and ≤9 on the 11-point NRS scale for the week immediately preceding Baseline Appointment(two readings); b. No score >9 on either reading preceding Baseline Appointment. 4. The subject has successfully completed the FIQ-R at least 2 times during the screening phase. a. A mean FIQ-R total score ≥35 and ≤80 on the 100-point FIQ-R scale for the week immediately preceding Baseline Appointment (two readings).
Efficacy and Safety Assessments/ Endpoints:	**<u>Efficacy assessments:</u>** ● **<u>Primary efficacy endpoint</u>** o The primary efficacy endpoint is the difference between the Group A and Group S in the mean change from baseline (CFB) at Week 12 on the weekly Revised Fibromyalgia Impact Questionnaire (FIQ-R) total score ● **<u>Key Secondary efficacy assessment:</u>** o Rate of Patient's Global Impression of Change (PGIC) Responders at Week 12 - Any Improvement **<u>Safety assessments:</u>** Safety assessments will include: ● Adverse events/ Unanticipated Adverse Device Effects ● Assessment of psychological status: o Beck Depression Inventory (BDI-II) o Columbia-Suicide Severity Rating Scale (C-SSRS)