
Overview

Motivista is a digital therapeutic smartphone app for patients with negative symptoms of schizophrenia. It is only intended to treat the negative symptoms of schizophrenia. Motivista requires a prescription from a healthcare provider.

Indications for Use

Motivista (CT-155) is a prescription digital therapeutic indicated for the treatment of negative symptoms of schizophrenia as an adjunct to clinician-managed outpatient care, including antipsychotic therapy, in patients 18 years of age and older with clinically stable positive symptoms.

Important Safety Information

Warnings

- Motivista is not designed to treat patients who present a serious suicide risk such as patients with active suicidal ideation with method or intent within the last 3 months or patients with suicidal behavior within the last 6 months or presentation with suicide risk (based on opinion of the clinician).
- Motivista is not designed to treat patients with unmanaged positive symptoms.
- Motivista is not intended to be used as a standalone therapy. It is meant to be used as an adjunct to clinician-managed pharmacotherapy for schizophrenia.
- Motivista does not replace or substitute the patient's medication, including medication for treatment of schizophrenia. Patients should continue their current treatment as directed.
- Motivista cannot send alerts or warnings to the prescriber. If patients feel that their schizophrenia symptoms are worsening or if they have feelings or thoughts of harming themselves or others, they should stop using the app and contact a healthcare provider, dial 988 (for mental health emergencies) or 911 (for medical emergencies), or go to the nearest emergency room immediately.
- A possibly-related Treatment Emergent Adverse Event (TEAE) was observed during Motivista's pivotal clinical study. Two events of "psychotic disorder" were considered possibly related to Motivista in a single participant, though neither led to study discontinuation.

Precautions

- The safety and effectiveness of Motivista have not been evaluated in:
 - patients with positive symptoms that are not well-controlled;
 - patients not taking antipsychotic medication;
 - patients with severe cognitive impairment who are unable to use the app independently;
 - patients who present a serious suicide risk, or;
 - patients less than 18 years of age.
- Motivista is not intended to be used for acute symptoms of schizophrenia.
- The sale, distribution, and use of Motivista are restricted to prescription use in accordance with 21 CFR 801.109.

Contraindications

- None known.

Patients 18 to 21 years old: Monthly monitoring is recommended during Motivista treatment due to potential for additional clinical risks and treatment needs of earlier stages of illness. When available, a caregiver, family member, or other member of the treatment team can serve as an additional source of support for this age group.

Prescribing Information

Please use your clinical judgment to determine whether Motivista is right for your patient. Motivista is for adjunctive use alongside a clinician-managed treatment plan for schizophrenia, which should include pharmacotherapy and clinical monitoring.

Important considerations include:

Prior to Treatment Initiation

The prescriber should confirm the following:

- The patient is proficient in written and spoken English.
 - Note: the Motivista app is currently only available in English. Patients who are otherwise clinically appropriate but not proficient in written and spoken English are not eligible for Motivista therapy at this time.
- The patient has access to a SMS-enabled smartphone, is able to use a smartphone independently, and is familiar with the use of smartphone apps.
- The patient is prescribed medication for schizophrenia and has well-controlled positive symptoms.

Patient Guidance

- Advise patients to read the Motivista Patient Instructions for Use before using the app.
- Advise patients to inform their healthcare provider of any changes to their current prescription or over-the-counter medications while using the app since Motivista is intended to be used alongside medication for schizophrenia.
- Advise patients to stop using the app and tell their healthcare provider if their symptoms worsen or using the app is causing them distress.
- Advise patients to contact a healthcare provider, dial 988 (for mental health emergencies) or 911 (for all other medical emergencies), or go to the nearest emergency room if they are experiencing a psychiatric or medical emergency.

Recommended Patient Monitoring During Treatment with Motivista

- Motivista is not intended to be used for acute symptoms of schizophrenia. It should be used for the treatment of negative symptoms of schizophrenia, as part of a treatment plan that includes clinician-managed pharmacotherapy. Prescribers should monitor patients as part of their treatment plan.
- *Patients 18 to 21 years old:* Monthly monitoring is recommended during Motivista treatment due to potential for additional clinical risks and treatment needs of earlier stages of illness. When available, a caregiver, family member, or other member of the treatment team can serve as an additional source of support for this age group.
- *App access and engagement:* At routine visits, it is recommended to ask the patient whether they are able to log in to and open the Motivista app, whether they are completing in-app activities as expected, such as the daily lessons, and whether they have encountered any technical barriers (e.g., connectivity issues). If the patient has been unable to engage with the app for multiple consecutive weeks, despite reasonable troubleshooting or technical support, providers should use their clinical judgment to reassess whether Motivista remains an appropriate component of the patient's treatment plan. For troubleshooting or technical support, please call +1 (855) 647-5187 or email motivista@clicktx.com.

Clinical Discontinuation Guidance

Motivista was studied in patients with a primary diagnosis of schizophrenia, who had clinically stable positive symptoms, and were on a stable antipsychotic medication dose for at least 12 weeks. Prescribers should consider discontinuing Motivista if a patient's clinical status no longer reflects this level of stability, including:

- Reemergence or worsening of positive symptoms (e.g., hallucinations, delusions, disorganized thinking)
- Transition of care to inpatient psychiatric hospitalization
- Non-adherence to prescribed antipsychotic medication
- Onset of a major depressive, manic, or hypomanic episode
- Emergence of moderate to severe substance use disorder
- Active suicidal ideation or behavior
- Sustained inability to engage with the app

If any of these occur, clinicians should use clinical judgment to determine whether Motivista remains an appropriate adjunct to the patient's treatment plan.

Product Overview

Motivista is a prescription digital therapeutic administered via the patient's smartphone device (running Apple or Android operating system) that incorporates multiple cognitive and behavioral interventions, approaches, and techniques and adapts them for digital delivery. Motivista is designed for use as a prescription therapy over an active treatment period of 16 weeks. It is expected that the app is used for about 10 minutes each day, with an adaptive schedule that adjusts if a day is missed to optimize the therapeutic journey for each patient.

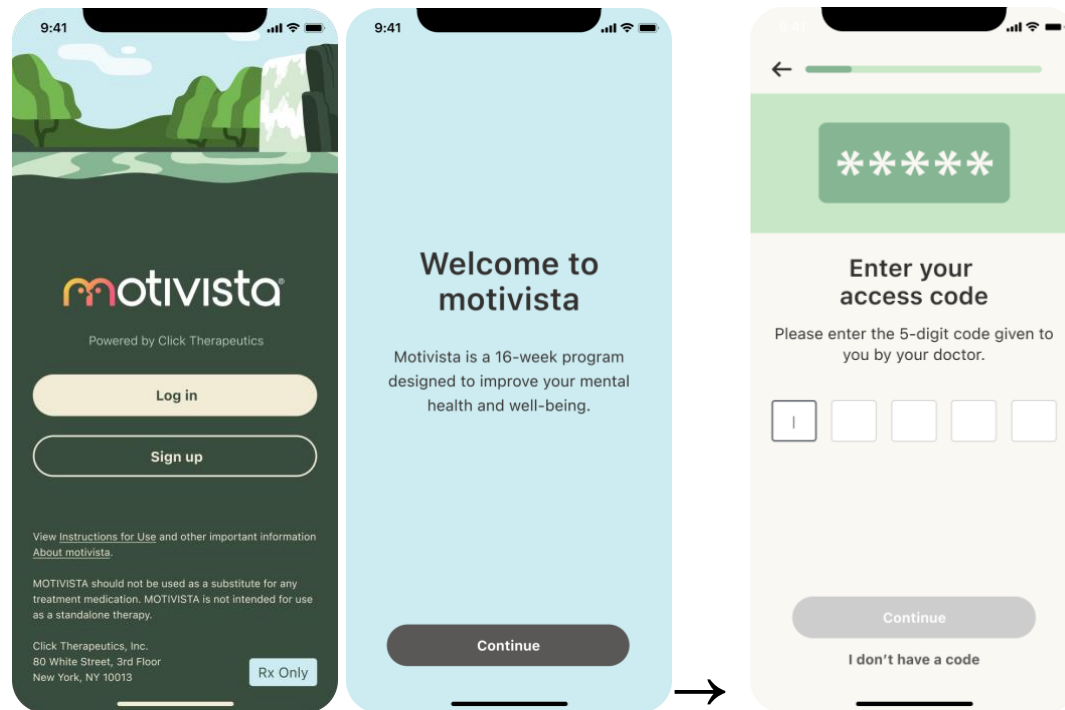
The software-based therapeutic intervention employs evidence-based cognitive and behavioral treatment components such as behavioral activation, cognitive restructuring, social skills training, positive affect training, and distress tolerance skills, alongside other digital interventions, approaches, and treatment techniques such as Adaptive Goal Setting and establishing a Digital Working Alliance process. Therapeutic delivery of Motivista is achieved through lessons, goal setting, personalized messaging, and tools, in a tailored therapeutic journey that is systematically structured to guide the patient towards a meaningful improvement in negative symptoms of schizophrenia.

Motivista is downloaded from the Google Play and Apple App Stores.

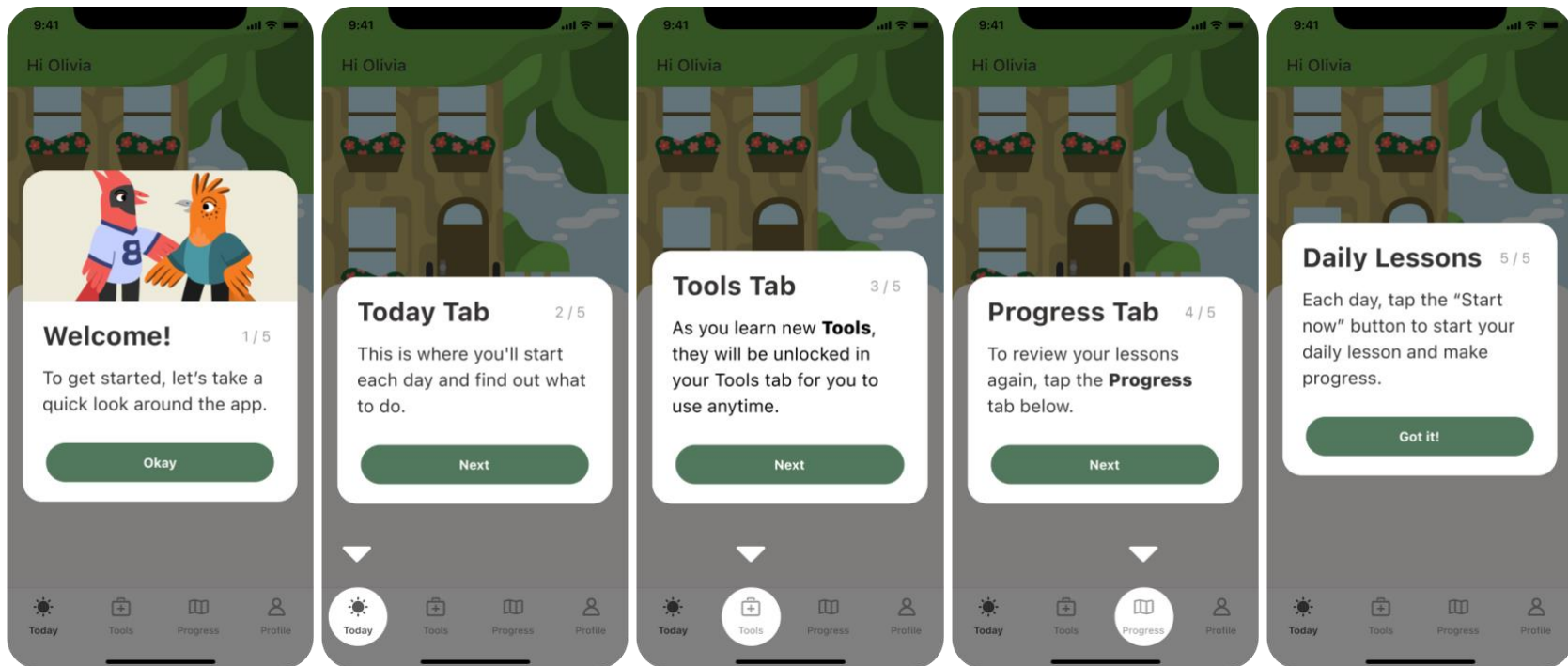
How to Start Using Motivista

- Motivista is intended for people with negative symptoms of schizophrenia who read and speak in English, have access to an SMS-enabled smartphone, are able to use a smartphone independently, and are familiar with the use of smartphone apps.
- The healthcare professional will submit a prescription for Motivista to a designated pharmacy for fulfillment.
- Once the Motivista prescription has been processed by the pharmacy, the patient will receive an access code that can be used to activate their prescription in the app.
- The patient will access the app by searching for and downloading Motivista from the Google Play or Apple App Store.

- The patient will create a user account by entering the unique access code and establishing account credentials including email, password, and phone number. The patient will need to verify their email and phone number to establish their account.



- Once the patient creates an account, they can access the program and begin treatment. They should be directed to follow the instructions provided in the app and in the Patient Instructions for Use.



- The patient will use the app to complete lessons, goals, tools and / or other activities daily for 16 weeks.
- Once the 16-week treatment period is over, lesson and tool content are available to be revisited for an additional 4 weeks, after which the patient will no longer be able to access Motivista.

Patient Instructions for Use

The Patient Instructions for Use (IFU) can be found at <https://motivista.com/patient-instructions-for-use.pdf> and gives additional information to help the patient navigate the initial steps within the app, including screenshots for setup and app use.

Supported Smartphones and Systems

The Motivista app runs on smartphones that are compatible with Android or iPhone operating systems (OS). Motivista operates with the following systems:

- Apple iOS 16 and greater
- Android OS 13 and greater

If the patient's smartphone is not running a compatible OS version, they will need to update their OS version before downloading and using Motivista.

Downloading Motivista requires at least 340MB of space on the patient's smartphone.

Motivista is not currently compatible for use with computers or tablets. If a patient cannot find Motivista in the Apple App Store or Google Play Store, their device may not be compatible.

Mechanism of Action for Motivista

The mechanisms of action (MOA) of Motivista in the treatment of negative symptoms of schizophrenia are hypothesized to remediate dysfunctions in rewards pathways, particularly those associated with reinforcement learning for positive rewards and reward anticipation (Bègue et al., 2020; Marder & Umbricht, 2023; Wu et al., 2021). Specifically, the fronto-striatal neural circuitry, especially the ventral striatum, is centrally involved in the goal-directed behavioral dysfunctions observed in negative symptoms (Bègue et al., 2020; Wu et al., 2021). Deficits in these reward pathways contribute to reduced internal representations of behavioral goals and lead to motivational impairments (Marder & Umbricht, 2023). This process contributes to onset and maintenance of the experiential negative symptoms of schizophrenia (avolition, anhedonia, and asociality).

Motivista is designed to remediate these processes by using a digital adaptation of behavioral activation and cognitive restructuring to increase engagement in pleasurable activities and improve the accurate association of pleasure and effort with goal-directed behaviors, in addition to targeting reward pathways (Jung & Han, 2024; Nagy et al., 2020; König et al., 2025). This is achieved in Motivista through tailored goal setting that aligns with each patient's current level of functioning (Adaptive Goal Setting) and promoting engagement in real-world activities (behavioral activation), while targeting

maladaptive cognitions such as defeatist performance beliefs (cognitive restructuring). Additionally, Motivista delivers therapeutic interventions to further facilitate successful goal attainment (social skills training, positive affect training, distress tolerance skills).

Motivista Features & Functionality

Motivista is a prescription digital therapeutic software-based therapeutic intervention that employs evidence-based cognitive and behavioral treatment components such as behavioral activation, cognitive restructuring, social skills training, positive affect training, and distress tolerance skills, alongside other digital interventions, approaches, and treatment techniques such as Adaptive Goal Setting and establishing a Digital Working Alliance process.

Motivista's journey is systematically structured to guide the patient towards a meaningful improvement in negative symptoms of schizophrenia. Therapeutic content is grouped into three phases: Orientation Phase (21 days in length), Goal Attainment Phase (84 days in length) and Consolidation Phase (7 days in length).

Treatment is delivered through lessons, goals, activities, tools, daily check-ins, and personalized messaging.

Lessons

Throughout treatment, Motivista delivers lessons that provide education on therapeutic concepts and skills, with at most one lesson presented each day. Lessons are grouped into modules based on therapeutic topics and may demonstrate behaviors related to the therapeutic concepts (e.g., using tools and activities for an active learning experience).

- In the Orientation Phase of treatment, Motivista delivers lessons containing therapeutic concepts and psychoeducation relating to behavioral activation, cognitive restructuring, positive affect training, and distress tolerance. These lessons are intended to set expectations and encourage daily adherence to tasks, provide schizophrenia-specific psychoeducation, introduce concepts and skills to help prepare the patient for engagement during the treatment, and build a strong Digital Working Alliance process to help establish trust that Motivista can help them make progress towards their goals.

- Following the Orientation Phase, the Goal Attainment Phase delivers lessons that provide social skills training through lesson content, and cognitive restructuring through pre- and post-activity ratings that support patients in developing balanced thinking patterns to increase the likelihood of successful activity completion.
- The Consolidation Phase also delivers lessons which are intended to guide the patient to reflect on and celebrate their progress over the course of treatment and establish a plan for the continued application of skills learned over the course of treatment in daily life.

Goals

During the Goal Attainment phase, the app sets goals for the patient to accomplish (e.g., introduce yourself to someone new, start a creative habit, do something on your to-do list). The goals are tailored to each patient and are set adaptively to gradually increase in difficulty as the patient acquires more skills. They are designed to encourage patient action and behavior related to the therapeutic techniques. Each goal consists of four distinct steps to help the patient progress incrementally towards their objectives by breaking the practice of the therapeutic techniques and goals into small, achievable steps that support successful goal attainment. At most one goal step is presented to the patient each day.

Activities

Within lessons and goal steps, Motivista includes activities for the patient to complete (e.g., cooking, taking out the trash, sending an email). Motivista explains the activity, guides the patient in practicing the activity, reinforces each practice of the activity, and where applicable helps the patient make a plan for how to complete the activity in daily life.

Tools

Skill-based tools are available as additional on-demand support to help patients manage cognitive emotional states that may negatively impact goal attainment. Tools are introduced in lesson content with examples to demonstrate the application, then are subsequently available for the patient to practice any time on-demand after they are first introduced.

Daily Check-Ins

Motivista includes a daily check-in that asks the patient about their mood and may recommend actions for the patient to take, like practicing relevant tools, based on the patient's current mood. The daily check-in may also ask the patient if they completed their previous activities and prompt the patient to reflect on the activity.

Personalized Messages

As part of the Motivista treatment program, the Motivista app sends SMS text messages and push- notifications that promote engagement with treatment by reinforcing lesson content, reminding patients to complete treatment-related lessons and goal steps, and encouraging completion of the program. Motivista learns from a patient's in-app activity to tailor and personalize these messages to align with their unique treatment journey.

Continued Access

Following the 16 weeks of treatment, patients have limited, continued access to the app for four weeks. During this time patients can still access lesson and tool content from the Motivista treatment period. After the four-weeks, patients will no longer have access to lesson and tool content.

Clinical Evidence

The indications for use for Motivista are supported by the results of a multi-center, randomized, double-blind (patients also blinded to hypothesis), digital-controlled clinical study (CT-155-R-001, also referred to as "CONVOKE"). The CONVOKE pivotal clinical study demonstrated that treatment with Motivista reduced negative symptoms of schizophrenia as evaluated by the Clinical Assessment Interview for Negative Symptoms, Motivation and Pleasure (CAINS-MAP) scale, without any device-related serious adverse events.

Study Population

The CONVOKE study enrolled participants (18 years or older) with at least a 6-month history of diagnosed schizophrenia per the Diagnostics and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), and who experienced moderate to severe negative symptoms. Participants were eligible if they had been on a stable dose of antipsychotic medication(s) for

12 weeks prior to randomization, were in the stable phase of illness (as assessed by the investigator after review of medical records or documented discussion with the treating healthcare provider, or from determination of the Principal Investigator), had stable housing for 12 weeks prior to screening, had outpatient treatment status at the time of screening and no inpatient treatment for schizophrenia within 12 weeks prior to screening, and had obtained an average score of ≥ 2 (moderate to severe) in at least two of the three CAINS-MAP domains (Social, Work or Recreational) at the Screening Visit and at baseline (Day 1).

Key exclusion criteria included (1) treatment with more than two antipsychotic medications, (2) prominent positive symptoms as indicated on the PANSS scale, (3) psychotherapy (current or within 13 weeks prior to screening), (4) DSM-5 diagnosis for schizophreniform, schizoaffective, psychosis non-specific disorders, current episode of depression/mania/hypomania, (5) moderate to severe substance use disorder (except tobacco; within 12 months prior to screening), and (6) active suicidal ideation with method or intent within the last 3 months or suicidal behavior within the last 6 months (as assessed by the C-SSRS) or presentation with suicide risk (based on opinion of the investigator).

Study Design

Participants took part in the study for up to 22 weeks, including a two-week Screening Period, 16-week Intervention Period, and up to four-week Follow-Up Period (see Figure 1).

After verification of preliminary eligibility in the Screening Period, participants were enrolled and granted access to a mobile application (the “Study App”). At baseline, participants were reassessed for eligibility and, if confirmed, were randomized in a 1:1 ratio to receive either the Motivista intervention or a Digital Control. In order to blind the study participants to both the study hypothesis and treatment assignment, access to both interventions was granted through the Study App and participants were informed that they would receive one of two investigational digital interventions. The Motivista intervention included lessons, goals, check-ins, and skill-based tools. The Digital Control included check-ins and lessons with disease-specific educational content that was designed to increase knowledge without encouraging behavior change or providing other therapeutic benefits. The Digital Control was designed as a comparable digital experience to match Motivista with similar daily participant engagement and frequency of app use.

During the Intervention Period, all randomized participants were expected to use the Study App daily. Participants in both arms also received messages prompting participants to maintain engagement with the Study App. Each day, participants were expected to complete at least one task in the Study App, and adherence was monitored.

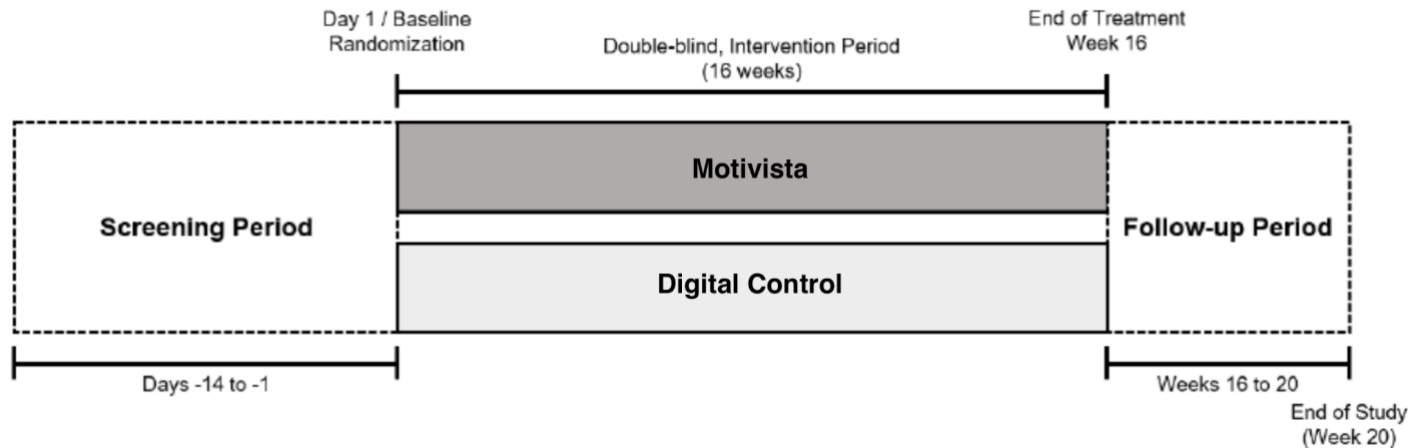


Figure 1. Study Design Schema for the Motivista's Pivotal Clinical Study

Outcome Measures

The primary objective of the pivotal clinical study was to evaluate the effectiveness and safety of Motivista in reducing negative symptoms, compared with a Digital Control, in participants diagnosed with schizophrenia. The primary effectiveness endpoint was the change from baseline to Week 16 in experiential negative symptoms, as assessed by Clinical Assessment Interview for Negative Symptoms, Motivation and Pleasure Scale (CAINS-MAP). Other clinical outcomes were evaluated as secondary endpoints at Weeks 8 and 16, such as change in motivation and pleasure symptoms at Week 8 as assessed by CAINS-MAP, change in expressive negative symptoms as assessed by Clinical Assessment Interview for Negative Symptoms, Expressivity Scale (CAINS-EXP), change in Positive and Negative Syndrome Scale (PANSS) total score, change in PANSS positive subscale, change in social functioning as assessed by Personal and Social Performance Scale (PSP), change in self-reported defeatist beliefs as assessed by the Defeatist Beliefs Subscale of the Dysfunctional Attitudes Scale (DAS), Patient Global Impression of Improvement Scale (PGI-I), and Patient Global Impression of Severity (PGI-S).

The primary effectiveness endpoint was evaluated using Mixed Model Repeated Measures (MMRM) on the intent-to-treat (ITT) analysis set, which included all unique participants randomized, based on observed data and was tested at a significance level of 0.05. All other effectiveness endpoints were tested at a nominal 0.05 level (2 sided) without adjusting for multiplicity.

Participant Disposition

Table 1 summarizes the various analysis sets used in the CONVOKE pivotal clinical study. In the CONVOKE study, of the 1,205 individuals screened for participation, 457 unique participants were randomized: 227 to the Motivista arm and 230 to the Digital Control arm (Intent-to-Treat [ITT] Set). The ITT Set was the primary population used for the effectiveness analyses. Participant demographics between the two arms were fairly balanced and were reflective of the intended patient population within the US. 62.6% of participants were male in the Motivista arm with 58.7% male in the Digital Control. The mean age at baseline was 45.8 (± 12.46) years; 46.2 (± 12.44) years in the Motivista arm and 45.3 (± 12.50) years in the Digital Control arm. The population was mostly Black or African American (53.4%) and White or Caucasian (39.6%) and was balanced across arms. Annual income was $< \$25,000$ per year in 63.5% of participants and 80.3% of participants were unemployed. At baseline, the majority of participants had a length of time since diagnosis of schizophrenia greater than five years (83.2%) and were taking only one antipsychotic medication (88%); of antipsychotic medication prescribed, most were second-generation antipsychotics (91.5%).

Supportive effectiveness analyses were also performed in a modified ITT (mITT) Set and a Per Protocol (PP) Set, as described in Table 1 below. Safety analyses were performed in the Safety Analysis Set, which included all participants who were exposed to Motivista or the Digital Control (i.e., completed at least one available daily activity in the Study App during the Intervention Period). In the CONVOKE study, the Safety Set consisted of 459 participants (n = 228 for Motivista arm; n = 231 for Digital Control arm).

Table 1. CONVOKE Study Analysis Sets

Analysis Set	Description	Motivista	Digital Control	Total
Intent-to-Treat (ITT)	All unique randomized participants	227	230	457
Modified Intent-to-Treat (mITT)	All unique randomized participants who completed at least one available daily activity in the Study App and have at least one post-baseline CAINS assessment	201	204	405
Per Protocol	All unique randomized participants who completed the treatment and at least one available daily activity in the Study App on at least 67 days during the Intervention Period without a major protocol deviation impacting the primary endpoint	119	152	271
Safety Set	All randomized participants completed at least one available daily activity in the Study App	228	231	459

Safety

Adverse events were reported by participants through communications with the research team and assessed for relatedness to Motivista by the investigator.

The overall rate of TEAEs was 7.9% in the Motivista arm and 11.7% in the Digital Control arm. Psychiatric disorders were reported as TEAEs in 2.0% of participants (three in the Motivista arm and six in the Digital Control arm). Of all the TEAEs, two events were considered to be possibly related to Motivista (one participant experienced two instances of “psychotic disorder”, neither of which led to study discontinuation) and one event was considered to be definitely related to the Digital Control (“irritability”, which led to study discontinuation). None of the TEAEs considered as related to the study intervention

were serious TEAEs. No TEAEs led to participant discontinuation in the Motivista arm, and two TEAEs led to participant discontinuation in the Digital Control arm.

Additionally, there were two TEAEs reported as serious for worsening “schizophrenia” in the Digital Control, but both were assessed as not related to the study intervention.

Effectiveness Summary

Data from CONVOKE indicates that Motivista provides a benefit in reducing negative symptoms to participants with negative symptoms of schizophrenia as an adjunct to clinician-managed antipsychotic therapy. CONVOKE’s primary effectiveness endpoint was the change in experiential negative symptoms from baseline to Week 16 as assessed by CAINS-MAP. CAINS-MAP is a 9-item Motivation and Pleasure subscale of CAINS, a 13-item, second-generation, semi-structured interview for assessing negative symptoms in schizophrenia. The pivotal study achieved study success by showing that the difference in the reduction in CAINS-MAP was statistically significant between Motivista and the Digital Control.

Primary Effectiveness Endpoint

In the pivotal study, CAINS-MAP decreased more from baseline to Week 16 in the Motivista arm (least square (LS) mean -6.8) than the Digital Control (LS mean -4.2). The -2.6 CAINS-MAP difference between the arms was statistically significant ($p=0.0003$). Similar outcomes were also observed in CAINS-MAP at 8 weeks with a greater reduction observed in Motivista (LS mean -5.3) than the Digital Control (LS mean -2.8) and a difference of -2.5 between arms.

The primary effectiveness results are provided in Table 2. The primary effectiveness results from the ITT analysis were supported by comparable results conducted on the mITT Set and PP Set, demonstrating the robustness of the findings.

Table 2. Primary Effectiveness Endpoint (ITT Set)

	Pivotal Study (CONVOKE)		
CAINS-MAP Change from Baseline to Week 16*	Motivista (N=196)	Digital Control (N=204)	Difference Between Arms
LS mean	-6.8	-4.2	-2.6
95% confidence interval (CI)	(-7.76, -5.77)	(-5.15, -3.18)	(-4.00, -1.20)
p-value	-	-	0.0003

*The primary effectiveness endpoint (change from baseline to Week 16 in CAINS-MAP total score) was analyzed using a prespecified Mixed Model Repeated Measures (MMRM) approach on the ITT set with observed data, i.e., that included subjects with at least 1 post-baseline CAINS-MAP assessment (Week 8 and Week 16). The number of participants whose longitudinal data directly inform the primary MMRM is 196 (Motivista) and 204 (Digital control). Two prespecified sensitivity analyses were conducted using the full ITT set with imputation (N=457; 227 Motivista + 230 Digital control). Missing CAINS-MAP values for all ITT participants — including the 57 with no post-baseline assessment — were multiply imputed under the MAR assumption, with the primary MMRM refit on each imputed dataset and results combined using Rubin's rule. A tipping-point analysis was also performed to evaluate robustness under a Missing Not at Random (MNAR) assumption. Both sensitivity analyses, conducted on the complete N=457 ITT population, corroborated the primary result, supporting that the treatment effect estimated from the 196/204 MMRM analysis population is representative of the full ITT population.

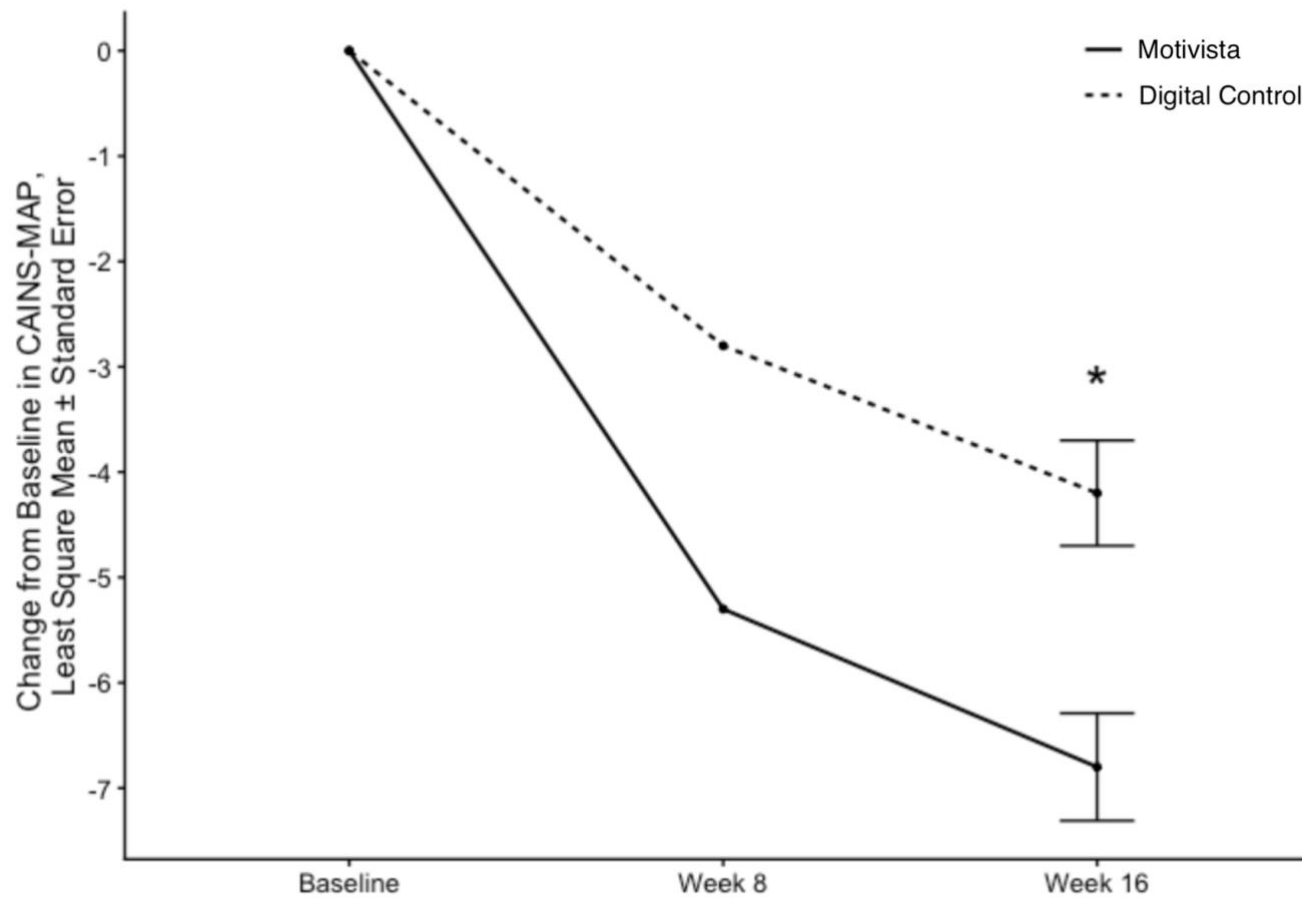


Figure 2. LS Mean Change from Baseline to Week 8 and 16 in CAINS-MAP (ITT Set)

* P-value = 0.0003

^a Secondary effectiveness endpoints included LS mean change from CAINS-MAP Baseline to Week 8; multiplicity adjustment and hypothesis testing were excluded from the analysis of secondary endpoints.

^b The primary effectiveness endpoint was LS mean change from Baseline to Week 16; the primary endpoint was analyzed with hypothesis testing.

Participant Engagement

Participant engagement data with Motivista was captured by the Study Application during the pivotal clinical study to characterize how study participants used and interacted with Motivista and the Digital Control. The results showed high levels of participant engagement with the application, with participants on average using the application over 60% of days during the 16-week treatment period. In both arms, the average number of days with at least one daily activity completed closely mirrored the data for the number of days the Study App was used, indicating that on almost all days that participants opened the app, they meaningfully engaged. In total, participants in the Motivista arm spent approximately an hour per week using the treatment, which is comparable to the typical time spent in conventional, in-person psychotherapy (e.g., 45 to 60 minute weekly sessions). Overall, these results indicate high engagement among patients with negative symptoms of schizophrenia and support the face-validity (believability) of the Digital Control in the pivotal clinical study.

Table 3. Study Application Engagement Metrics (ITT Set)

	Motivista	Digital Control
Number of days the app was used, mean (%) ^a	68.5 (61.2)	80.1 (71.5)
Number of days with at least one daily activity completed, mean (%) ^{a,b}	66.1 (59.0)	79.2 (70.7)

^a Percentages calculated based on total number days during Intervention Period = 112 days.

^b Qualifying daily activities in Motivista included completing lessons, completing check-ins, practicing skill-based tool practice, and/or steps to attain goals. Daily activities in the Digital Control included completing lessons and/or completing check-ins.

Conclusion

In conclusion, data from the Motivista clinical study indicates that Motivista provides benefit to participants with negative symptoms of schizophrenia as an adjunct to clinician-managed antipsychotic therapy. The CONVOKE pivotal study achieved study success by showing that the difference in the reduction of experiential negative symptoms as assessed by CAINS-MAP was statistically significant between Motivista and the Digital Control. Reduction of CAINS-MAP was 2.6 points greater in Motivista as compared to Digital Control. There were no serious device related adverse events, and a very low incidence of suicidal ideation or behavior was observed in both arms. Although worsening psychotic symptoms that may

have been related to Motivista were observed during the study, neither caused sufficient harm to cause participants to leave the study. The only study discontinuation due to suicidal ideation occurred in the Digital Control arm. Clinical evidence supports that Motivista is safe and effective for the treatment of negative symptoms in schizophrenia.



Manufacturer Address:

Click Therapeutics, Inc.
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New York, NY 10013



Motivista is only available for prescription use.

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