# Clinician Information
## Brief Summary Instructions

### Stanza®

Prescription Digital Therapeutic Mobile Application

### Indications for Use Statement

Stanza is a Prescription Digital Therapeutic that provides Acceptance and Commitment Therapy, a form of Cognitive Behavioral Therapy, and is indicated for the treatment of fibromyalgia symptoms in adult patients.

The therapy also improves the symptoms of depression, anxiety, and sleep quality in adult patients with fibromyalgia

### What is Stanza?

Stanza is a self-guided prescription digital smartphone application that delivers Acceptance and Commitment Therapy (ACT), a form of Cognitive Behavioral Therapy (CBT), to patients with fibromyalgia.

ACT and CBT are utilized in the treatment of chronic pain conditions, including fibromyalgia. In the context of fibromyalgia and other chronic pain conditions, ACT teaches acceptance and mindfulness strategies for uncontrollable symptoms, together with commitment and behavior-change strategies to prevent symptom flares, increase quality of life, and improve physical and emotional functioning.

ACT guides individuals to change their expectations from the elimination of pain to managing their pain and living as well as possible with it.

Stanza is available by prescription only.

### Who Should Use Stanza?

Stanza is intended for patients who:

- Are age 22 or older
- Diagnosed with fibromyalgia
- Can read and understand English
- Have regular access to a smartphone with functional audio
- Are under the supervision of a Health Care Provider

### Who Should Not Use Stanza?

Patients should not use Stanza if they:

- Have severe, untreated depression
- Are at risk of harming themselves

### How Should Stanza Be Used?

Stanza is intended to be used five to seven days per week, for approximately 15 to 20 minutes a day, for a period of 12 weeks (3 months). After 12 weeks, Stanza may be used as needed.

### Important Safety Information

Stanza is not a medical or psychological service and is not equipped to provide crisis services. No human is monitoring a patient's input into the application.

Patients should be instructed that Stanza cannot be used to communicate with their healthcare provider.

In case of a crisis or medical emergency, patients should be instructed to go to their local emergency room, call 911, or contact the National Suicide Prevention Lifeline: 988 or 1-800-273-8255.

Stanza is not intended to replace care by the provider and is not a substitute for other fibromyalgia treatments.

### How to Start Using Stanza

The following steps will help guide the patient's use of Stanza:

- You will prescribe Stanza by ordering / sending the prescription and providing patient contact information to XRHealth.
- To activate Stanza, your patient will need to download the application from the Apple or Android application store and entering their registered e-mail address or an access code.
- Once logged in, the patient will go through an introduction to Stanza and can start using the application.

## What Smartphones Does Stanza Support?

Stanza is supported on the following smartphone operating systems:

- Apple iPhone with iOS12 or higher
- Smartphone running Android 8 or higher

If your patient's smartphone is not running an operating system matching those above, instruct them to update their operating system before downloading and using Stanza.

Stanza is not supported on tablet devices nor laptop or desktop computers.

## Summary of Clinical Testing

Stanza has been evaluated in several clinical studies.

In the PROSPER-FM randomized, controlled trial (NCT05243511), 275 participants meeting the 2016 ACR diagnostic criteria for fibromyalgia were randomized to Stanza or a control application. At week 12, significantly more participants reported improvement in their fibromyalgia in the Stanza arm than those in the control arm, demonstrated by the response rate on the Patient Global Impression of Change (PGIC) (70.6% vs 22.2%, $p<0.001$, Intent-to-treat analysis). Stanza also met the key secondary endpoint, with a greater reduction in fibromyalgia impact on the Revised Fibromyalgia Impact Questionnaire (FIQ-R) total score than the control arm (least-squares mean change of −10.27 vs −2.24 points; difference −8.04, $p<0.001$).

In PROSPER-FM, symptoms of depression, anxiety, and sleep were assessed as additional endpoints. Results at week 12 are summarized below.

**Depression**: Participants in the Stanza arm had significantly greater improvement in depressive symptoms than participants in the control arm on the Beck Depression Inventory-II (BDI-II) and on the 0–10 depression item of the FIQ-R.

**Sleep**: Participants in the Stanza arm had significantly greater improvement in sleep disturbance than participants in the control arm on the PROMIS Sleep Disturbance Short Form 6a and on the 0–10 FIQ-R sleep quality item. Weekly sleep interference favored Stanza but did not reach statistical significance ($p=0.049$; significance threshold 0.046).

**Anxiety**: Participants in the Stanza arm had greater improvement than participants in the control arm on the 0–10 FIQ-R items for anxiety and feeling overwhelmed.

In the SMART-FM randomized, controlled trial (NCT05005351), 67 participants meeting the 2016 ACR diagnostic criteria for fibromyalgia were randomized to Stanza or a control application. At week 12, significantly more participants in the Stanza arm reported improvement in their fibromyalgia than those in the control arm, measured by PGIC (73.0% vs 22.2%, $p<0.001$, Intent-to-treat analysis).

The control arm in both PROSPER-FM and SMART-FM included patient education and symptom tracking which are known tools for management of fibromyalgia and other pain symptoms.

No Stanza-related adverse events were observed in either the PROSPER-FM and SMART-FM trials.

## What Additional Support Is Available?

For additional support or questions on Stanza, you can contact XRHealth by e-mail at support@xr.health or by phone at:

1 (888) 977-6828

Stanza® is the property of XRHealth R&D Ltd.
© 2026 XRHealth R&D Ltd.
All rights reserved.

**Rx Only**

Legal Manufacturer:

XRHealth R&D Ltd.
32 Schocken, Floor 2
TEL AVIV Tel Aviv 6105101
Israel