Patient 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 in adult patients.

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?

Do not use Stanza if you:

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

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 your input into the application.

Stanza cannot be used to communicate with your healthcare provider.

In case of a crisis or medical emergency, you should go to your local emergency room, call 911, or contact the National Suicide Prevention Lifeline at 988 or 1-800-273-8255.

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

How to Start Using Stanza

The following steps will help guide your use of Stanza:

- Your clinician will prescribe Stanza to you through the XRHealth clinician platform.
- Download the application from the Apple or Android application store.
- To log in, enter the e-mail address associated with your prescription, accept the Terms of Use and Privacy Policy, and then enter the six-digit one-time code sent to that address. No password or access code is required.
- Once logged in, your first session begins with a short welcome lesson that introduces Stanza and explains how the program works.

What Smartphones Does Stanza Support?

Stanza is supported on the following smartphone operating systems:

- Apple iPhone with iOS 12 or higher
- Smartphone running Android 8 or higher

If your smartphone is not running an operating system matching those above, please update your 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), 90 participants meeting the 2016 ACR diagnostic criteria for fibromyalgia were randomized to Stanza or an active control application (a digital symptom tracker). 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) (64.7% vs 21.0%, $p<0.001$, Intent-to-treat analysis).

Similarly, 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 (a digital symptom tracker). 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 22.0%, $p<0.001$, Intent-to-treat analysis).

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

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Legal Manufacturer:
XRHealth R&D Ltd.
32 Schocken, Floor 2
TEL AVIV-JAFFA 6655613
Israel